

OFFICIAL TITLE:

Virtual reality to improve low-back pain and pelvic pain during pregnancy: study protocol for a multicentre randomized controlled trial.

NTC NUMBER: DK/NA

DATE DOCUMENT: 12/06/2022

Authors: Francisco José García-López<sup>1\*</sup>, José Manuel Pastora-Bernal<sup>2</sup>, Noelia Moreno Morales<sup>2</sup>, María José Estebanez-Pérez<sup>3</sup>, María del Carmen Rodríguez-Martínez<sup>4</sup>, and Rocío Martín-Valero<sup>2</sup>

<sup>1</sup>Department of Physiotherapy, Faculty of Health Science, University of Malaga, 29071 Málaga, Spain [fjgarlop@gmail.com](mailto:fjgarlop@gmail.com) (F.-J.G.-L.)

<sup>2</sup>Department of Physiotherapy, Faculty of Health Science, University of Malaga, 29071 Málaga, Spain [jmpastora@uma.es](mailto:jmpastora@uma.es) (J.-M.P.-B.) [nmm@uma.es](mailto:nmm@uma.es) (N.M.-M.) [rovalemas@uma.es](mailto:rovalemas@uma.es) (R.M.-V.)

<sup>3</sup>Department of Physiotherapy, Faculty of Health Science, University of Granada, 18071 Granada, Spain [mariajoseestebanezperez@gmail.com](mailto:mariajoseestebanezperez@gmail.com) (M.-J.E.-P.)

<sup>4</sup>Department of Physiotherapy, Faculty of Health Science, University of Malaga, 29071 Málaga, Spain [marrodmar@uma.es](mailto:marrodmar@uma.es) (M.-C.R.-M.)

\*Correspondence: [fjgarlop@gmail.com](mailto:fjgarlop@gmail.com); (F.-J.G.-L.)

## ABSTRACT

A large percentage of women suffer low back and pelvic pain both during and after pregnancy. There are several factors to which these complaints are attributed, even affecting their daily lives. It is identified that many of these women do not receive adequate health care, however, different physiotherapeutic interventions are recommended to alleviate these conditions, presenting moderate levels of evidence. Virtual reality is presented as a complementary and promising treatment method to physiotherapy for the improvement of fundamental variables such as perceived pain and pain avoidance. The main objective is to evaluate the efficacy of a combined VR and physiotherapy program of 4 weeks duration compared to a standard physiotherapy intervention in pregnant women with low back pain and pelvic pain for the improvement of pain avoidance, pain intensity, disability and functional level. As a secondary objective we propose to investigate patient satisfaction with the VR intervention. This research will be carried out by means of a multicenter randomized controlled clinical trial in pregnant patients residing in the provinces of Seville and Malaga with a diagnosis of low back pain and pelvic pain during pregnancy. The alternative hypothesis of this research is that the implementation of a Virtual Reality program together with standard physiotherapy in pregnant patients with low back and pelvic pain presents better clinical results obtained with the current standard intervention, which may represent an opportunity to define new policies and interventions for these pathologies and their consequences.

## KEYWORDS

Virtual Reality, Physiotherapy, Low-back pain, Pelvic pain, Pregnancy

## Background

Approximately 50% of women experience low back pain (LBP) during pregnancy; 25% continue to experience pain 1 year after delivery (1). Low-back pain (LBP) and pelvic pain (PP) are common during pregnancy and tend to increase as pregnancy advances; in some cases, the pain radiates into the buttock, leg and foot (2). Global prevalence is reported to range from 24% to 90%, in part, because there is currently no universally recognised classification system for the condition (3). For many women, pain can become so severe that it interferes with ordinary daily activities, disturbs sleep with repercussions in social and sexual life, work capacity and increased psychological stress and contributes to high levels of sick leave (4). Several factors have been identified as the possible causes of back pain in pregnancy. Mechanical strain secondary to enlarge gravid uterus is one of the causative factors which leads to compensatory lumbar lordosis (5). Besides that, separation of the abdominal muscles during pregnancy does contribute to paraspinal muscle strain. Relaxin hormone which is elevated during pregnancy is also identified as a causative factor. Hence, there will be an increase in joint laxity which may caused instability rotatory movements of sacroiliac joints (6,7).

It is estimated that over 50% of women receive little or no intervention from healthcare providers (8). European guidelines recommend that LBP and PP, are managed by providing adequate information and reassurance to patients that it is best to stay active, continue normal daily activities and work if possible, and by offering individualised exercises where appropriate. Similarly, prenatal practitioners in the United Kingdom and Nordic countries give women information about how to manage LBP, PP or both during their pregnancy and may refer them to physiotherapy for a more specific treatment programme. However, in the United States, women are taught that LBP is a normal part of pregnancy. Interventions that have been used to date to help manage the pain include exercises, frequent rest, hot and cold compresses, abdominal or pelvic support belts, massage, acupuncture, chiropractic, aromatherapy, relaxation, herbs, yoga, Reiki, paracetamol, and nonsteroidal anti-inflammatory drugs (3,4,8,9). Other forms of therapy have been studied including exercise, yoga, progressive muscle relaxation, manual therapy, acupuncture, alone or with exercises, multi-modal

approach, including manual therapy, exercise and education, pelvic belts, kinesio tape and transcutaneous electrical nerve stimulation (TENS). A Cochrane systematic review and metanalisis from 2015 conclude that there is low-quality evidence that exercise may reduce pregnancy-related low-back pain and moderate to low-quality evidence suggesting that any exercise improves functional disability and reduces sick leave more than usual prenatal care (2). Another Systematic review from 2018 including 32 studies conclude that compared with not exercising, prenatal exercise decreased the severity of LBP, PP, during and following pregnancy (1).

Some studies addressed the issue of sick leave during pregnancy, presenting positive results through exercise programs, reducing healthcare costs and promoting women's health (10,11). Recommended physical treatments, particularly for persistent low back pain (>12 weeks duration), include a graded activity or exercise programme that targets improvements in function and prevention of worsening disability. Since evidence showing that one form of exercise is better than another is not available, guidelines recommend exercise programmes that take individual needs, preferences, and capabilities into account in deciding about the type of exercise. Some guidelines do not recommend passive therapies, such as spinal manipulation or mobilisation, massage, and acupuncture, some consider them optional, and others suggest a short course for patients who do not respond to other treatment (12). Other passive electrical or physical modalities, such as ultrasound, transcutaneous electrical nerve stimulation progressive relaxation, and mindfulness-based stress reduction and combined packages of physical and psychological treatment, for those with persistent LBP who have not responded to previous treatments (13–15). For patients who have not responded to firstline treatments, and who are substantially functionally disabled by pain, multidisciplinary rehabilitation programmes with coordinated delivery of supervised exercise therapy, cognitive behavioural therapy, and medication are more effective than standard treatments (13–18).

A clinical practice guidelines in LBP during pregnancy in Spain suggests the use of aquatic exercises and other individualized exercise programs, as well as therapeutic massage to relieve low back pain during pregnancy (19). Furthermore,

physiotherapy was effective in relieving back pain by increasing the strength of the lumbo-sacral joint and pelvic girdle muscles (20). By introducing exercise as one of the treatments for back pain in pregnancy, it is hope to reduce the pain suffered by these women and hence reduce the morbidities associated with it. It is also aims to improve the quality of life (6).

Virtual Reality: Virtual reality (VR) is a new technology, which has been rapidly evolving over the past 2 decades (21). VR can be operationally defined as “simulations that make use of various combinations of interaction devices and sensory display systems” (22,23). VR has been explored in a variety of fields and clinical applications. In healthcare, VR technology can be used to provide treatment (24), facilitate pain management (25) and rehabilitation (12) among others.

A systematic review from 2019 conclude that VR has the potential to improve outcomes for spinal pain with demonstrated statistical and clinical significance (26). Additional patient populations with benefit from VR interventions include individuals with higher pain and physical dysfunction levels, anxiety, an alternative treatment to opioid analgesics (26). A randomized control trial in 80 female patients with breast cancer at a specialized cancer center in Jordan shown that immersive VR is an effective distraction intervention for managing pain and anxiety. Using immersive VR as an adjuvant intervention is more effective than morphine alone in relieving pain and anxiety (27). In stroke patients VR show promise as a future tool in the rehabilitation of daily live activities, particularly in the subacute phase (27). VR allows the user to experience the interaction with a computer-generated environment and the simulation of realistic environments and real-life exercises (26). In the rehabilitative context, motivation is an important factor influencing the performance outcome (26). VR constitutes an enriched environment with augmented multiple sensory feedbacks (auditory, visual, tactile), with moving avatars, engaging several neuronal circuits that potentiate patient's learning and recovery (28–30). Thus, VR may be considered a good candidate to help patients in improving their own movements, body position perception and reducing pain during the VR exercises (31). A systematic review from 2019 focus on orthopedic rehabilitation conclude that the evidence of VR effectiveness is promising in chronic neck pain and shoulder impingement syndrome. VR and exercises have

similar effects in rheumatoid arthritis, knee arthritis, ankle instability, and post-anterior cruciate reconstruction. For fibromyalgia and knee arthroplasty, the evidence of VR effectiveness compared to exercise is absent or inconclusive (32). A recent Systematic review from 2020 suggest that VR exercise has the potential to exert a positive impact on individual's physiological, psychological, and rehabilitative outcomes compared with traditional exercise (33). VR can also be used for various purposes in different stages of pregnancy: reducing their anxiety levels and training them to effectively manage their pain during labor (34), reducing anxiety before cesarean, episiotomy repair, dilation and curettage (35–38), reducing pain (29), and managing exercise training (24).

Despite the fact that VR has been shown to be effective in some orthopedic conditions, there is no evidence about the effectiveness of VR interventions in LBP and PP during pregnancy. Considering the current health, it is advisable to carry out VR effectiveness studies in this group population both in the hospital environment and in other areas of care.

## Objectives

The main objective of this research is to evaluate the effectiveness of a combined VR and Physiotherapy 4-weeks program compared to a standard physiotherapy intervention in LBP and PP pregnancy woman's to improve pain-related fear avoidance, pain intensity, disability and functional level.

The secondary aim is to investigate patient satisfaction with the VR intervention.

## Methods

### Study design and setting

This research is a 4-week prospective multicentre randomized clinical trial. Participant recruitment and the supervised VR program component will be provided by clinical setting at department of Physiotherapy at University of Sevilla and Málaga (Spain). This research involves departments of gynecology rehabilitation, physiotherapy and researches from the University of Granada,

University of Málaga and University of Sevilla. This research follow the guidelines on Standards for Quality Improvement and Excellence in Reporting (SQUIRE) (39) and is carried out in accordance with CONSORT (Consolidated Standards of Reporting Trials) criteria (40).

The study was approved by the institutional ethics committee of Andalucía with internal code 1928-N-21. All female participants must provide informed consent prior to enrollment in the study.

#### [Participants and eligibility criteria](#)

The trial includes pregnant women suffering from LBP, PP or the two in combination as reported symptomatically by the women or diagnosed by clinicians.

Patients must live in Sevilla or Málaga during the intervention phase, patients with history of LBP or lumbar pathology before pregnancy or have suffered LBP or PP events prior to the first contact with this research. Patients will be excluded if they have any absolute or relative contraindications such as heart disease, chronic obstructive lung disease, diabetes mellitus, incompetent cervix/cerclage, multiple gestation, risk of premature labor, preeclampsia/pregnancy-induced hypertension, thrombophlebitis, pulmonary embolism, intrauterine growth restriction, or serious blood disease, history of abortion or curettage. Also, patients are not in full cognitive capacity that allows them to use new technology tools will be excluded. Inclusion and exclusion criteria is show in Table 1.

Inclusion criteria	Exclusion criteria
Adult woman over 18 years old	Patients with LBP or PP pain prior to pregnancy.
Pregnant woman with Low Back Pain, Pelvic Pain or both conditions with symptomatic character.	Cognitive ability not suitable for the use of technological tools.
Pregnant woman between the 12th and 36th week of gestation, corresponding to the 2nd and 3rd trimester.	Patients with absolute or relative contraindications.
Pain intensity greater than 4/10 on VAS, indicating moderate-severe pain.	
Live in Sevilla or Málaga during the research period.	

Table 1. Inclusion and Exclusion criteria

### Recruitment

In order to generate sufficient data for the development of this research a sample size of (n= 66) patients will be recruited based on previous and concluded RCT for the treatment of LBP or PP (41–43). It was calculated that a sample size of 33 women per cohort could detect a difference in outcomes of 1.0 between the VR intervention and control groups, given a SD of 1.5 and a power of 0.80.

The strategies to achieve an adequate inclusion of participants that reach the target sample size include the multidisciplinary collaboration of the gynecology, rehabilitation and physiotherapy department. The collaborators have been informed about the characteristics of the study in personal interviews and presentation. Recruitment of patients must have a socio-demographic diversity in relation to their social origin, gender, ethnicity and education adapted to the particularities of the reference population.

### Intervention

Participants will be assigned randomly to the intervention or control groups using a random number table. Both groups will receive 3 sessions per week during the 4 weeks of intervention.

## Control Group (CG)

Following clinical practice guidelines, subjects in the control group will receive multidisciplinary rehabilitation programmes with coordinated delivery of supervised exercise therapy, cognitive behavioural therapy (education on pain), as well as therapeutic massage to relieve low back pain during pregnancy.

Typical physiotherapy session:

- Control of daily health
- Analgesic and muscle-relaxing (thermotherapy, tens, therapeutic massage)
- Exercise session:
  - o Initial warm-up: 5–10 min (thoracic, lumbar and pelvic joint mobility exercises adapted to the pregnancy progress).
  - o Strengthening and flexibility exercises (thoracic, lumbar and pelvic joint exercises adapted to the pregnancy progress).
  - o Return to calm: 5 min breath and stretching exercises
  - o Recording of incidents and patient/physiotherapist feedback

Experimental Group (EG). VR intervention:

- o Subjects in the experimental group will receive the same treatment described for the control group
- o Subjects in the experimental group will receive an additional VR intervention.

The immersive virtual reality (VRi) system is composed by a head mounted display (Oculus Quest, Facebook Inc.) and two controllers. Oculus Quest headset is a wireless and portable Android-based device which supports positional tracking with six degrees of freedom (360°). The internal cameras allow to show an external signal with the user view, which helps to monitoring the patient execution. A Wi-Fi connection and a training area of 2x2 meters are needed.

At the end of each session, participants will experience an immersive virtual landscape displayed by Nature Trek VR software (<https://naturetreksvr.com/>). First, participants will be placed in a sit down position and guided for their breathing control during 5 minutes (“meditation Lotus option”). After that, they will be encouraged to freely move around a relaxing virtual environment during 15 minutes taking special attention to soothing sounds of nature. The themed environment will be selected based on the preferences of the participants.

At the beginning of the study, advice is given on general care, in physical activity and issues concerning drug intake. Patients are advised to refrain from any other specific training during the intervention period. Any deviations from the adherence and practice of the VRi are recorded daily, noting any adverse incidents.

## [Outcomes and Instruments](#)

### [Primary research outcomes](#)

- Pain-related fear avoidance (FACS): The Fear-Avoidance Components Scale (FACS) was developed, which incorporates important components of previous FA-related measures, and includes components of the FA model not previously considered in the earlier-developed questionnaires, within a framework of the most current FA model of Vlaeyen (44,45). The FACS has demonstrated acceptable test/retest reliability ( $r = .90\text{--}.94$ ) and internal consistency (Cronbach  $\alpha=.92$ ) (46).

Pain-related fear avoidance (FA), a common problem for patients with painful medical conditions, involves pain-related catastrophizing cognitions, hypervigilance, and avoidance behaviors, which can ultimately lead to decreased functioning, depression, and disability (47).

- Pain intensity: (Visual Analogue Scale VAS): The VAS has been used in previous studies investigating changes in pain and, specifically, in all the randomized trials of interventions for back pain in pregnancy included in or published since the Cochrane and systematic reviews (42). The visual analog scale (VAS) was used for assessment of pain before and after the intervention. Measurement will be performed with a 10-cm scale marked with 1-cm increments. Pain felt by participants will be recorded. Pain was rated on a scale of 0 a 10, with 10

representing the most excruciating pain. The value indicated on the scale by the participants was used as the score. Previous studies have shown that the reliability of the VAS ( $r=0.76-0.84$ ) is high (46).

- Disability and Physical function: In this paper, we focus on the 2 back-specific measures of function recommended in the “core-set,” the Roland-Morris disability Questionnaire (RMDQ) and the Oswestry Disability Index (ODI). They are the most commonly used measures of function in back pain research (46).

The RMDQ will be used for measurement of the severity of disability in participants who had less severe LBP. There are 24 categories comprised of yes or no questions. Each participant can have a maximum score of 24. Scoring closer to 24 indicates greater functional disability (48,49). Quoted test-retest correlations include 0.91 (same day), 0.88 (1 week), and 0.83 (3 weeks) (48).

The Oswestry low-back pain disability index (ODI) will be completed by the participants and included 10 questions assessing activities of daily living in order to examine the functional level when experiencing LBP. Each category will be scored from zero to five with regard to the severity of disability caused during daily life. The intraclass correlation coefficient was  $r=0.938$ , and the Cronbach’s alpha was 0.918 (day 1) and 0.895 (day 7) in the validation (44,45).

#### Secondary research outcomes

- Satisfaction with Virtual Reality intervention

To assess the Satisfaction with the Virtual Rehabilitation Systems we will use the USEQ (User Satisfaction Evaluation Questionnaire). The USEQ is a questionnaire that is designed to properly evaluate the satisfaction of the user (which constitutes part of usability) in virtual rehabilitation systems. The USEQ is a reliable questionnaire with adequate internal consistency, Cronbach alpha coefficient was 0.716, and patients found the USEQ to be an easy-to-understand questionnaire with a convenient number of questions (50).

Primary and Secondary Outcomes	Definition	Type
Pain related fear avoidance	FACS	Self-reported
Pain intensity	VAS	Registered / Self-reported
Disability and physical function	RMDQ, ODI	Registered / self-reported
Satisfaction and usability	USEQ	Self-reported

Table 2. Primary and Secondary Outcomes

#### Data collection, monitoring, and management

Once participants have been informed and agree to participate in the study, data will be collected for statistical analysis. This data collection will take place in the period September-December 2022. Initial assessment (Pre) and final 4-week assessment (Post) will be carried out by the research team including, rehabilitation and physiotherapy department. The data will be aggregated to research database created for this purpose and managed by the principal's researches using exportable data tables for statistical analysis.

The research is designed in 4 stages as presented at Figure 1 study design flow diagram:

Stage 1 includes 2 different processes: firstly the identification of candidates, the provision of prior information and the signing of informed consent if subjects agree to participate. Secondly, the assessments by the physiotherapy department. The initial assessment includes a self-made clinical interview for anamnesis with self-administered questionnaires, which will be completed including FACS, RMDQ, ODI and VAS (T0-Pre). This stage ends with the referral to the physiotherapy intervention team.

Stage 2 includes: Design of a personalised physiotherapy programme (CG and EG) according with Physiotherapy department plus VRi intervention in the (EG).

Stage 3 includes: 4 weeks physiotherapy intervention plus VRi program with the supervision of the physiotherapy department. Initials 1 to 1 session is offered with technology management and patient education. Daily follow up sessions include the progression and adverse events records. Physiotherapy team will update programmes according to participant's feedback.

Stage 4 includes: Final assessments and evaluation (T1-Post). At this stage Physiotherapy team and principals researches compile the results of outcomes after 4 weeks including FACS, RMDQ, ODI, VAS and USEQ. Satisfaction questionnaire will be added to research data's for statistical analysis.

#### [Statistical analysis](#)

This research is a multicentre prospective controlled trial pre/post design. The results of the trial research will be presented as a summary of the outcome measures, together with the estimated effect size and precision. Statistical analysis will be performed according to the intention-to-treat principle. Patient characteristics will be summarized using frequencies and percentages for categorical factors, and using means and standard deviations for continuous measures in order to have as much information as possible available for exploration and analysis. The effect sizes will be calculated using the Cohen's d so that the results can be compared to other studies. The outcome measures will be compared before and after the completion of the 4 weeks program. All statistical analyses will be conducted using SPSS software. Statistical significance was set at  $p < 0.05$ .

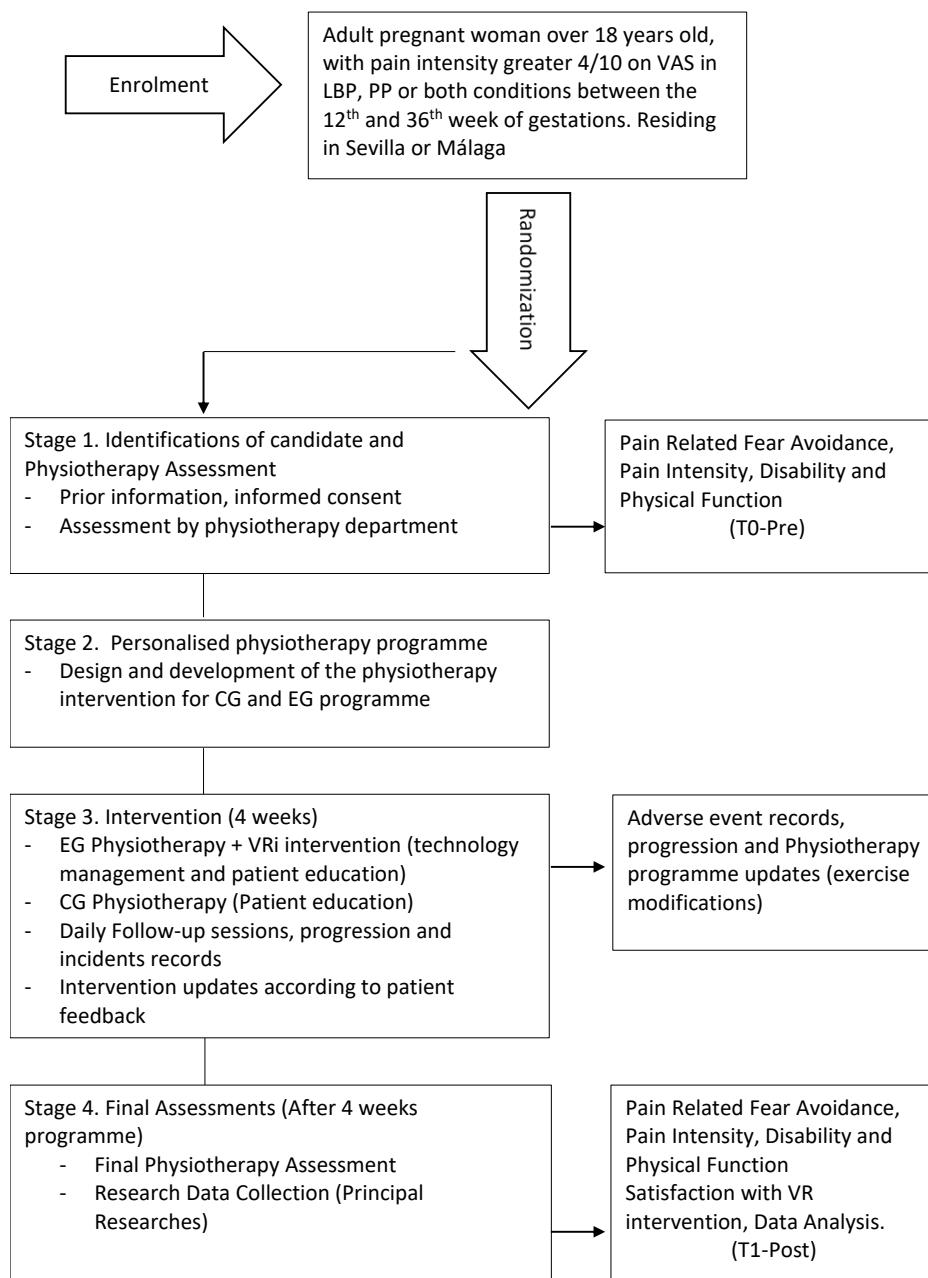


Figure 1. Study design flow diagram: Enrollment, assessments and intervention stages

## Results:

Enrollment began in September 2022. First study results will be reported at the end of 2022. The results of this study will determine if a larger-scale intervention is feasible. Further, this pilot study will be the first to examine the effect of the VR intervention on LBP and PP in pregnancy woman. If the results confirm beneficial

effects in the outcomes, this study will add more evidence in support of the use of VR program as an effective tool in pregnancy with LBP and PP rehabilitation programs.

#### Discussion:

Evidence from single studies suggests that some therapy modalities or a multi-modal intervention (manual therapy, exercise and education) improves pelvic pain and pregnancy related outcomes. However, the current scientific evidence leaves many issues unresolved like type and intensity of exercise and physiotherapy intervention effectiveness for different outcomes. Since evidence showing that one form of exercise is better than another is not available, guidelines recommend exercise programmes that take individual needs, preferences, and capabilities into account in deciding about the type of exercise. This lack of standardized exercise programmes may lead to significant intervention biases in the different studies and consequently the low or moderate level of evidence.

Due to the high prevalence, the recurrence, the interference on daily activities, work capacity and sick leaves, and the increased psychological stress (1–4), low back pain is undoubtedly the key clinical sign to address in this population.

The VRi used in this case may alleviate pain by distracting the patient's attention from pain. The alleviation of pain is thought to be the psychological effect of immersion in the virtual space created by the VR technology (51). Another mechanism by which the VR program can reduce pain would be the creation of a relaxing atmosphere. Perception of pain is influenced by the patient's affect (52). Therefore, the positive effect induced by the psychological effects of the VR relaxation program could suppress pain perception (53).

This research should provide knowledge about the possibility of implementing VR programs in clinical environment, identifying new intervention opportunities in this group of patients.

Technical problems like device failures and technological difficulties may arise in connection with the use of VR technology. However, staff members are available to provide technical support. As possible adverse events we consider

the lack of improvement and positive evolution of the patient. We also consider as an adverse event the performance of exercise with excessive workload. Patients will be informed of the importance of warning the health professional of any incident or setback in their recovery and their right to withdraw from participation in the research at any time.

Future lines of research would involve the development of clinical trials with a large sample size and the opportunity to develop a multicenter randomized clinical trial with standardize physiotherapy and exercise programmes

#### Conclusions:

This study protocol is the first to examine the effect of a VR intervention added to physiotherapy in LBP and PP in a multicentre clinical setting. Efficacy and satisfaction must show if this study will add more evidence in support of the use of VR as an effective tool in pregnancy women.

#### Ethical aspects

This project will be carried out following the guidelines of the Declaration of Helsinki (Fortress 2013) and the Standards of Good Clinical Practice. Personal data will be processed according to REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data; and the Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights (54). Only researchers will have access to the research data. The information collected from each subject will be associated with a numerical identification code and will be the only identification of the patient for the purposes of data processing and analysis.

This trial has the approval of the Andalucía Ethics Committee with HIP version 1928-N-21.

#### Informed Consent Statement:

Participants in the study are required to read and approve the consent form by signing the previous information for patients and the consent form. They will also be informed of the possibility of revoking the consent given at any time, without having to justify their decision and without prejudice.

Confidentiality of data: The Researcher declares that follows the protocols of his work centre regarding the publication of data in accordance with the provisions of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights, and that the data will be incorporated into a file for the purpose of carrying out this research project.

[\*\*Conflict of interest.\*\*](#)

No conflict of interest

## References

1. Davenport MH, Marchand AA, Mottola MF, Poitras VJ, Gray CE, Jaramillo Garcia A, et al. Exercise for the prevention and treatment of low back, pelvic girdle and lumbopelvic pain during pregnancy: A systematic review and meta-analysis. Vol. 53, British Journal of Sports Medicine. BMJ Publishing Group; 2019. p. 90–8.
2. Liddle SD, Pennick V. Interventions for preventing and treating low-back and pelvic pain during pregnancy. Vol. 2015, Cochrane Database of Systematic Reviews. John Wiley and Sons Ltd; 2015.
3. Vermani E, Mittal R, Weeks A. Pelvic girdle pain and low back pain in pregnancy: A review. Vol. 10, Pain Practice. Blackwell Publishing Inc.; 2010. p. 60–71.
4. Engeset J, Stuge B, Fegran L. Pelvic girdle pain affects the whole life - A qualitative interview study in Norway on women's experiences with pelvic girdle pain after delivery. BMC Res Notes. 2014 Oct 3;7(1):1–7.
5. Moon WN. :: KRSpine :: Journal of Korean Society of Spine Surgery [Internet]. [cited 2021 Jun 18]. Available from: <https://www.krspine.org/search.php?where=aview&id=10.4184%2Fjkss.2000.7.2.259&code=0089JKSS&vmode=FULL>
6. Abu MA, Abdul Ghani NA, Shan LP, Sulaiman AS, Omar MH, Ariffin MHM, et al. Do exercises improve back pain in pregnancy? Horm Mol Biol Clin Investig. 2017 Dec 20;32(3).
7. To WK, Wong MWN. Factors associated with back pain symptoms in pregnancy and the persistence of pain 2 years after pregnancy. Vol. 82, # Acta Obstet Gynecol Scand. 2003.
8. Sinclair. How do women manage pregnancy-related low back and/or pelvic pain? Descriptive findings from an online survey — Ulster University [Internet]. [cited 2021 Jun 14]. Available from: <https://pure.ulster.ac.uk/en/publications/how-do-women-manage-pregnancy-related-low-back-and-or-pelvic-pain--3>
9. Airaksinen O, Brox JI, Cedraschi C, Hildebrandt J, Klaber-Moffett J, Kovacs F, et al. Chapter 4: European guidelines for the management of chronic nonspecific low back pain. Vol. 15, European Spine Journal. 2006. p. 192–300.
10. Norén L, Östgaard S, Nielsen TF, Östgaard HC. Reduction of sick leave for lumbar back and posterior pelvic pain in pregnancy. Spine (Phila Pa 1976). 1997 Sep 15;22(18):2157–60.
11. KW. L. Therapeutic exercise in low back pain. J Korean Acad Rehabil Med 1995;19:203–8.
12. Rosa M, Manzanares MTL, Vergara CR, Casuso-Holgado MJ, Martín-Valero R.

The Use of Virtual Reality Technologies in the Treatment of Duchenne Muscular Dystrophy: Systematic Review. *JMIR Mhealth Uhealth* 2020;8(12):e21576. <https://mhealth.jmir.org/2020/12/e21576>. 2020 Dec 8;8(12):e21576.

13. Overview | Low back pain and sciatica in over 16s: assessment and management | Guidance | NICE.
14. A Q, TJ W, RM M, MA F. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med.* 2017 Apr 4;166(7):514–30.
15. MJ S, P K, J H, A K, J A, M A, et al. National Clinical Guidelines for non-surgical treatment of patients with recent onset low back pain or lumbar radiculopathy. *Eur Spine J.* 2018 Jan 1;27(1):60–75.
16. SJ K, AT A, A C, RJ S, RW O, J G, et al. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain. *Cochrane database Syst Rev.* 2014 Sep 2;2014(9).
17. JJ W, P C, DA S, K R, H Y, S V, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. *Eur J Pain.* 2017 Feb 1;21(2):201–16.
18. Foster NE, Anema JR, Cherkin D, Chou R, Cohen SP, Gross DP, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet.* 2018 Jun 9;391(10137):2368–83.
19. Guía de práctica clínica de atención en el embarazo y puerperio.
20. Garshasbi A, Faghih Zadeh S. The effect of exercise on the intensity of low back pain in pregnant women. *Int J Gynecol Obstet.* 2005 Mar 1;88(3):271–5.
21. Bolte B, De Lussanet M, Lappe M. Virtual reality system for the enhancement of mobility in patients with chronic back pain.
22. Chen KB, Sesto ME, Ponto K, Leonard J, Mason A, Vanderheiden G, et al. Use of Virtual Reality Feedback for Patients with Chronic Neck Pain and Kinesiophobia. *IEEE Trans Neural Syst Rehabil Eng.* 2017 Aug 1;25(8):1240–8.
23. Brodbeck D, Degen M, Stanimirov M, Kool J, Scheermesser M, Oesch P, et al. Augmented feedback system to support physical therapy of non-specific low back pain. *Commun Comput Inf Sci.* 2010;52:381–93.
24. Setiawan A, Agiwhahuanto F, Arsiwi P. A virtual reality teaching simulation for exercise during pregnancy. *Int J Emerg Technol Learn.* 2019;14(1):34–48.
25. Vinayak, Warty RR, Sursas JA, Payne O, Nair A, Krishnan S, et al. The Effectiveness of Virtual Reality in Managing Acute Pain and Anxiety for Medical Inpatients: Systematic Review. *J Med Internet Res* 2020;22(11):e17980

<https://www.jmir.org/2020/11/e17980>. 2020 Nov 2;22(11):e17980.

- 26. Ahern MM, Dean L V., Stoddard CC, Agrawal A, Kim K, Cook CE, et al. The Effectiveness of Virtual Reality in Patients With Spinal Pain: A Systematic Review and Meta-Analysis. Vol. 20, *Pain Practice*. Blackwell Publishing Inc.; 2020. p. 656–75.
- 27. Bani Mohammad E, Ahmad M. Virtual reality as a distraction technique for pain and anxiety among patients with breast cancer: A randomized control trial. *Palliat Support Care*. 2019 Feb 1;17(1):29–34.
- 28. Solouki S, Pooyan M. Arrangement and Applying of Movement Patterns in the Cerebellum Based on Semi-supervised Learning. *Cerebellum*. 2016 Jun 1;15(3):299–305.
- 29. Ito M, Doya K. Multiple representations and algorithms for reinforcement learning in the cortico-basal ganglia circuit. Vol. 21, *Current Opinion in Neurobiology*. Elsevier Current Trends; 2011. p. 368–73.
- 30. Kommalapati R, Michmizos KP. Virtual reality for pediatric neuro-rehabilitation: Adaptive visual feedback of movement to engage the mirror neuron system. In: *Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS*. Institute of Electrical and Electronics Engineers Inc.; 2016. p. 5849–52.
- 31. Alemano F, Houdayer E, Emedoli D, Locatelli M, Mortini P, Mandelli C, et al. Efficacy of virtual reality to reduce chronic low back pain: Proof-of-concept of a nonpharmacological approach on pain, quality of life, neuropsychological and functional outcome. *PLoS One*. 2019 May 1;14(5):e0216858.
- 32. Guma M, Youssef AR. Is Virtual Reality Effective in Orthopedic Rehabilitation? A Systematic Review and Meta-Analysis. Vol. 99, *Physical Therapy*. Oxford University Press; 2019. p. 1304–25.
- 33. Qian J, McDonough DJ, Gao Z. The effectiveness of virtual reality exercise on individual's physiological, psychological and rehabilitative outcomes: A systematic review. Vol. 17, *International Journal of Environmental Research and Public Health*. MDPI AG; 2020. p. 1–17.
- 34. Hajesmael-Gohari S, Sarpourian F, Shafiei E. Virtual reality applications to assist pregnant women: a scoping review. *BMC Pregnancy Childbirth* 2021 211. 2021 Mar 25;21(1):1–8.
- 35. Sridhar A, Shiliang Z, Woodson R, Kwan L. Non-pharmacological anxiety reduction with immersive virtual reality for first-trimester dilation and curettage: a pilot study. <https://doi.org/10.1080/13625187.2020.1836146>. 2020 Nov 1;25(6):480–3.
- 36. Frey DP, Bauer ME, Bell CL, Low LK, Hassett AL, Cassidy RB, et al. Virtual Reality

Analgesia in Labor: The VRAIL Pilot Study - A Preliminary Randomized Controlled Trial Suggesting Benefit of Immersive Virtual Reality Analgesia in Unmedicated Laboring Women. *Anesth Analg.* 2019 Jun 1;128(6):E93–6.

37. Shourab, Zagami SE, Golmakhani N, Mazlom SR, Nahvi A, Pabarja F, et al. Virtual reality and anxiety in primiparous women during episiotomy repair. *Iran J Nurs Midwifery Res.* 2016 Sep 1;21(5):521.
38. Lore, Goossens SMTA, Truijens SEM, Berckel MMG van, Perquin CW, Slooter GD, et al. A Virtual Reality Video to Improve Information Provision and Reduce Anxiety Before Cesarean Delivery: Randomized Controlled Trial. *JMIR Ment Heal* 2019;6(12)e15872 <https://mental.jmir.org/2019/12/e15872>. 2019 Dec 18;6(12):e15872.
39. Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney S, SQUIRE Development Group. Publication guidelines for quality improvement in health care: evolution of the SQUIRE project. *Qual Saf Health Care.* 2008 Oct;17 Suppl 1:i3-9.
40. Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJW, CONSORT Group for the. Reporting of Noninferiority and Equivalence Randomized Trials. *JAMA.* 2006 Mar 8;295(10):1152.
41. Kaplan Ş, Alpayci M, Karaman E, Çetin O, Özkan Y, İlter S, et al. Short-term effects of kinesio taping in women with pregnancy-related low back pain: A randomized controlled clinical trial. *Med Sci Monit.* 2016 Apr 18;22:1297–301.
42. Kalus SM, Kornman LH, Quinlivan JA. Managing back pain in pregnancy using a support garment: A randomised trial. *BJOG An Int J Obstet Gynaecol.* 2008 Jan;115(1):68–75.
43. Peterson CD, Haas M, Gregory WT. A pilot randomized controlled trial comparing the efficacy of exercise, spinal manipulation, and neuro emotional technique for the treatment of pregnancy-related low back pain. *Chiropr Man Ther.* 2012 Jun 13;20:18.
44. unit R. Oswestry Low Back Pain Disability Questionnaire.
45. Scoring the Oswestry Disability Index.
46. Cuesta-Vargas AI, Neblett R, Gatchel RJ, Roldán-Jiménez C. Cross-cultural adaptation and validity of the Spanish fear-avoidance components scale and clinical implications in primary care. *BMC Fam Pract* 2020 211. 2020 Feb 27;21(1):1–9.
47. Bombardier C, Hayden J, Beaton DE. Minimal clinically important difference. Low back pain: outcome measures. *J Rheumatol.* 2001;28(2).
48. M R, J F. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine (Phila Pa 1976).* 2000 Dec 15;25(24):3115–24.
49. A C, LJ M, CB T, GA W, P T, RW O. Roland-Morris Disability Questionnaire and

Oswestry Disability Index: Which Has Better Measurement Properties for Measuring Physical Functioning in Nonspecific Low Back Pain? Systematic Review and Meta-Analysis. *Phys Ther.* 2016 Oct 1;96(10):1620–37.

50. All B et. Minimal clinically important difference. Low back pain: outcome measures - PubMed [Internet]. [cited 2021 Jul 5]. Available from: <https://pubmed.ncbi.nlm.nih.gov/11246692/>
51. N A, H R, H C, A G, C V, P P. Virtual Reality interventions for acute and chronic pain management. *Int J Biochem Cell Biol.* 2019 Sep 1;114.
52. PH F, EL G. The role of positive affect in pain and its treatment. *Clin J Pain.* 2015 Feb 21;31(2):177–87.
53. H F, M T, R M, M S. Virtual reality applied to home-visit rehabilitation for hemiplegic shoulder pain in a stroke patient: a case report. *J Rural Med JRM.* 2021;16(3):2021–003.
54. Chassang G, Rial-Sebbag E. Research Biobanks and Health Databases: The WMA Declaration of Taipei, Added Value to European Legislation (Soft and Hard Law). Vol. 25, *European Journal of Health Law.* Brill Nijhoff; 2018. p. 501–16.

## APPENDIX I. INFORMED CONSENT

### **Informed Consent - Patient's Written Consent**

I (Name and Surname): .....

1. I declare that I have read the Patient Information Sheet that accompanies this consent.
2. I have been able to ask questions about the study. All questions were answered to my satisfaction.
3. I have spoken with the reporting health care professional:  
.....
4. I understand that my participation is voluntary and I am free to participate or not in the study.
5. I have been informed that all data obtained in this study will be confidential and will be treated in accordance with the Organic Law on Personal Data Protection 3/2018.
6. I understand that I can withdraw from the study:
  - Whenever I want
  - Without having to give explanations
  - Without affecting my medical care.

I freely give my agreement to participate in the project entitled

I GIVE

I DO NOT GIVE

Signature of the patient

Signature of the informing health professional

Name and surname:.....  
Data:.....

Name and surname:.....  
Data:.....

## APPENDIX II. PREVIOUS INFORMATION FOR THE PATIENT

**TITLE:** "Virtual reality to improve low back and pelvic pain during pregnancy: study protocol for a multicenter randomized controlled trial".

Department of Physiotherapy, Faculty of Health Sciences, University of Granada. Principal Research: Francisco José García López, ffigarlop@gmail.com, Tf: 695 33 29 91

**WHY ME?** Because you are over 18 years of age and have recently been selected by ..... So the research team has considered that you can benefit from the means offered to you from this research project.

**WHAT DOES THE PROJECT CONSIST OF?** An intervention accepted and validated by the scientific community is applied. Similar studies have shown that it can be a beneficial tool and that it can have positive effects or in any case never be detrimental to your condition. We want to test its effectiveness in certain patients, as well as to know if its implementation is satisfactory.

### **HOW ARE THE PARTICIPANTS ORGANIZED AND WHAT DOES THE INTERVENTION CONSIST OF?**

Participants will be randomly assigned to the intervention or control groups through the generation of random numbers by means of computer software. Both groups will receive 3 sessions per week for 4 weeks of intervention. Subjects in the experimental group will receive the same treatment as described for the control group, consisting of: multidisciplinary rehabilitation program, supervised exercise therapy, cognitive-behavioral therapy and therapeutic massage for pain relief. Subjects in the experimental group will receive an additional VR intervention at the end of the conventional physical therapy session.

### **CAN IT CAUSE ME DISCOMFORT?**

This intervention does not have to produce discomfort, beyond the sensations typical of a physiotherapy rehabilitation. In any case, if you feel even the slightest sensation, let your consultant know and you will be informed of the care you will receive.

### **WHAT HAPPENS IF I DECIDE TO APPLY OTHER MEASURES IN ADDITION?**

Your consultant will inform you during the research period what type of medical care you will receive and how you should report any other type of intervention that may influence the results.

### **WHAT HAPPENS AFTER THE WEEKS OF INTERVENTION?**

Your consultant during the research period will inform you of the recommendations to follow once the intervention is over.

**IF I DON'T FEEL LIKE IT, I CAN'T, I DON'T WANT TO CONTINUE IN THE STUDY, WHAT HAPPENS?** You can decide at any time your inclusion or exclusion from the project without giving any explanation if you wish to do so.

### **WHAT GUARANTEES DO I HAVE IF I DECIDE TO PARTICIPATE?**

In addition, the monitoring will be exhaustive by researchers with more than 20 years of professional experience.

### **Basic information on Data Protection**

In accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council, and of the Organic Law on Personal Data Protection 3/2018 and Guarantee of Digital Rights we inform you that the personal data provided will be processed exclusively by the Principal Investigator and members of the research team.

Rights: you have the right to access, rectify and delete the data, as well as other rights that you can exercise by contacting the address [fjgarlop@gmail.com](mailto:fjgarlop@gmail.com).