

INVESTIGACIÓN APLICADA EN SALUD: SOLUCIONES EMERGENTES PARA LA PRÁCTICA CLÍNICA

Comps.

María del Mar Molero Jurado
María del Mar Simón Márquez
Ana Belén Barragán Martín
Pablo Molina Moreno
Silvia Fernández Gea

Investigación aplicada en salud: Soluciones emergentes para la práctica clínica

Comps.

María del Mar Molero Jurado

María del Mar Simón Márquez

Ana Belén Barragán Martín

Pablo Molina Moreno

Silvia Fernández Gea

© Los autores. NOTA EDITORIAL: Las opiniones y contenidos de los textos publicados en el libro “Investigación aplicada en salud: Soluciones emergentes para la práctica clínica”, son responsabilidad exclusiva de los autores; así mismo, éstos se responsabilizarán de obtener el permiso correspondiente para incluir material publicado en otro lugar, así como los referentes a su investigación.

Edita: ASUNIVEP

ISBN: 979-13-87910-41-9

Depósito Legal: AL 1111-2026

Imprime: Artes Gráficas Salvador

Distribuye: EDITORIAL ASUNIVEP

No está permitida la reproducción total o parcial de esta obra, ni su tratamiento informático, ni la transmisión de ninguna forma o por ningún medio, ya sea electrónico, mecánico, por fotocopia, u otros medios, sin el permiso previo y por escrito de los titulares del Copyright

CAPÍTULO 1

Atención inicial al paciente politraumatizado en el servicio de urgencias: Abordaje sistematizado y el rol de enfermería

Dolores Olmo Lugo, Isabel Camacho Carrasco, Montserrat Gutiérrez Martín, Ester Canut Fusté, y Elina Garibyan 11

CAPÍTULO 2

Relación entre la evolución del edema macular diabético y cambios de la hemoglobina glicosilada en pacientes con retinopatía diabética

Álvaro Cristóbal Marín Lozano 21

CAPÍTULO 3

La autopráctica de enfermería quirúrgica de un hospital de tercer nivel

Martha Mariana Sánchez Lagunas, Catherine Valerdi Juárez, Erika Lozada Perezmitre, Asunción Menes González, Diana Capol Cabrera, y María del Rosario Ricardez Ramírez..... 29

CAPÍTULO 4

Injertos en sello para el tratamiento de las úlceras crónicas de los miembros inferiores: Revisión de la evidencia científica

Sara Zúnica García y Nuria Padrós Flores 35

CAPÍTULO 5

Efectos de la Fisioterapia sobre la formación ósea en bebés prematuros: Ensayo clínico multicéntrico aleatorizado

Galaad Torró Ferrero, Francisco Javier Fernández Rego, Daniel Ángel García, Sergio Montero Mendoza, José Manuel García Moreno, e Inmaculada Calvo Muñoz..... 45

CAPÍTULO 6

Vinculación entre las patologías del embarazo pre-eclampsia y diabetes gestacional y el desarrollo de autismo en la descendencia

Belén Monge Ochoa, Pilar Argente Arizón, Cristina Gil Roa, Pablo Jesús Bascuas Burges, Pilar Garralaga Clemente, Estela Sanguesa Sanguesa, Laura Lomba Eraso, Estefanía Zuriaga Marco, Beatriz Giner Parache, y Marta Serrano Megías 53

CAPÍTULO 7

Comparación entre predicciones in silico (modelo pkCSM) y fichas técnicas de fármacos utilizados en dermatitis atópica

Laura Lomba Eraso, Belén Monge Ochoa, Estela Sanguesa Sanguesa, Pilar Argente Arizón, Marta Serrano Megías, Pilar Garralaga Clemente, Estefanía Zuriaga Marco, Marta Sánchez Uzuriaga, Santiago Martínez Fierro, y Beatriz Giner Parache..... 63

CAPÍTULO 8

La Podología como pilar estratégico de la Salud Comunitaria: Prevención, educación sanitaria y promoción del Autocuidado

Enrique Panera Rico, Alejandro Roás Bernal, José Algaba del Castillo, y Fernando Chacón Giráldez 71

CAPÍTULO 9

Inteligencia Artificial y análisis de la marcha: Aplicaciones emergentes en Podología

Enrique Panera Rico, Fernando Chacón Giráldez, Alejandro Roás Bernal, Ana Juana Pérez Bellosó, y José Algaba del Castillo..... 81

CAPÍTULO 10

Modelado bioinformático y evaluación comparativa de la temozolomida y la 5-etinil-2'-desoxiuridina como agentes terapéuticos contra el glioblastoma

Santiago Martínez Fierro y Laura Lomba Eraso..... 89

CAPÍTULO 11

Validación de los diagnósticos enfermeros dolor crónico y síndrome de dolor crónico: Proyecto de investigación

Rocío Cáceres Matos, Elvira Suárez Casado, y Manuel Pabón Carrasco..... 99

CAPÍTULO 12

Efectos de la semaglutida sobre la masa magra en adultos con diabetes tipo 2 y/u obesidad: Revisión sistemática y meta-análisis

Pablo Jesús Bascuas Burges, Estela Sanguesa Sanguesa, Belén Monge Ochoa, Eduardo Piedrafita Trigo, César Berzosa Sánchez, Juan Rabal Pelay, Adriana Duaso Iriarte, y Luis Alberto Marco Contreras 109

CAPÍTULO 13

Conocimiento sobre primeros auxilios de los árbitros de fútbol federados de la provincia de Jaén

Ganna Ovsyeyenko, Cristina Fernández Martínez, Lucía Ortega-Donaire, y Jessica Bailen Expósito 119

CAPÍTULO 14

Desarrollo y evaluación de Sistemas Eutécticos Profundos Terapéuticos (THEDES) con potencial antiinflamatorio y permeación cutánea para el tratamiento tópico de la dermatitis atópica

Pilar Garralaga Clemente, Estela Sanguesa Sanguesa, Belén Monge Ochoa, Pilar Argente Arizón, Estefanía Zuriaga Marco, Álvaro Werner Josa, Marta Serrano Megías, Beatriz Giner Parache, y Laura Lomba Eraso 127

CAPÍTULO 15

Design, Implementation, and Evaluation of a Multicomponent Diaphragm Rehabilitation Project for Chronic Non-Specific Low Back Pain: A Two-Phase Randomized Controlled Trial

Francisco José Vera Serrano & Carlos Manuel Pérez Pérez..... 137

CAPÍTULO 16

Distracción no farmacológica en la Venopunción en urgencias: Una revisión sistemática

Ganna Ovsyeyenko, Lucía Ortega-Donaire, Jéssica Bailén Expósito, y Cristina Fernández Martínez..... 147

CAPÍTULO 17

Inteligencia artificial en la detección precoz y prevención de enfermedades: Evidencia actual y desafíos para su integración en la práctica clínica

Soffia Peralta Tavera, Imane Et Tamimi, Lucía Solares Puente, Sofia Ortiz Gandarillas, Alejandra Lavín Muner, y Claudia Basterrechea Diego 157

CAPÍTULO 18

Influencia de la gelificación de sistemas eutécticos profundos sobre la biodisponibilidad de principio activos

Álvaro Werner Josa, Laura Lomba Eraso, Pilar Argente Arizón, Estefanía Zuriaga Marco, Marta Serrano Megías, y Beatriz Giner Parache..... 167

CAPÍTULO 19

Comparación de arquitecturas de redes neuronales para el diagnóstico de cáncer de seno a través de imágenes de termografía infrarroja

Carlos Enrique Álvarez Salazar y Ana Rubiela Romero Castellanos 177

CAPÍTULO 20

Caracterización clínica del ictus en adultos: Etiología, factores asociados e implicaciones para la enfermería

Blanca Espina Jerez y Paula Gutiérrez Díaz..... 185

CAPÍTULO 21

Intervalos de referencia del cociente de cadenas ligeras libres séricas ajustados al filtrado glomerular en el mieloma múltiple y trastornos relacionados

Alicia Carazo García, Celia García Carro, y Rubén Tejel Puisac..... 195

CAPÍTULO 22

Creación de un repositorio virtual de Casos Clínicos Podológicos para la evaluación del aprendizaje clínico de los estudiantes del Grado en Podología

Irene Sanz Corbalán, Aroa Tardáguila García, Raúl Juan Molines Barroso, y José Javier López Marcos 203

CAPÍTULO 23

Empleo del Biomarcador S100 en la estratificación del riesgo de Lesión Intracraneal tras TCE Leve

Rubén Tejel Puisac, Celia García Carro, y Alicia Carazo García..... 211

CAPÍTULO 24

Impacto de la tutoría par como estrategia educativa en la formación integral del estudiante de enfermería

Johana Guadalupe Casas Recendiz, Teresita de Jesús Muñoz Torres, Nayelly de Jesús Martínez Martell, y Héctor López Gama..... 217

CAPÍTULO 25

Clústeres de pruebas diagnósticas y razonamiento clínico en Fisioterapia musculoesquelética: Evaluación de una Biblioteca Digital Complutense como innovación docente

Aroa Tardáguila García e Ibai López de Uralde Villanueva 227

CAPÍTULO 26

Resiliencia y apoyo social percibido asociados a la satisfacción vital en cuidadores informales

Marina del Rocío Ramírez Zhindón 235

CAPÍTULO 27

Development of an integrated cellular biomarker panel to assess retinal pigment epithelium damage and therapeutic response in Dry Age-Related Macular Degeneration

Gema Martínez Navarrete, Vanessa Zorrilla-Muñoz, Nicanor Morales Delgado, Raquel García López, & Ana Isabel Pombero García 243

CAPÍTULO 28

El ser humano detrás del uniforme: Experiencias emocionales y corporales durante la formación práctica en enfermería

Eyra Guadalupe Padrón Mata, Teresita de Jesús Muñoz Torres, Diana Laura Ramos Patiño, y Héctor López Gama253

CAPÍTULO 29

Eficacia de la Fisioterapia en mujeres con Dispareunia Profunda: Una revisión sistemática

Alba Marcos Hernández, Ander García García, Raúl García González, y Raquel Leirós Rodríguez.....261

CAPÍTULO 30

Redes sociales y salud mental adolescente: Una revisión sistemática

Silvia Fernández Gea, Elena Martínez Casanova, Pablo Molina Moreno, María del Mar Molero Jurado, y Ana Belén Barragán Martín271

CAPÍTULO 15

Design, Implementation, and Evaluation of a Multicomponent Diaphragm Rehabilitation Project for Chronic Non-Specific Low Back Pain: A Two-Phase Randomized Controlled Trial

Francisco José Vera Serrano* & Carlos Manuel Pérez Pérez**

**Servicio Andaluz de Salud; **Universidad de Cádiz*

Introduction

Project Description

Current State of the Issue (State of the Art)

Chronic non-specific low back pain (CNLBP) remains one of the leading causes of disability worldwide, generating a substantial burden on healthcare systems, working populations, and individual quality of life, with recent global estimates indicating a continued rise in age-standardized prevalence and years lived with disability over the past three decades (GBD 2021 Low Back Pain Collaborators, 2023; Chiarotto & Koes, 2022). Despite decades of clinical and biomechanical research, the multifactorial nature of CNLBP continues to challenge the identification of a single dominant mechanism, and current evidence increasingly points toward impaired neuromuscular control of the lumbopelvic complex as a central contributor to symptom persistence and recurrence, as first demonstrated by delayed feedforward activation of the transversus abdominis in individuals with low back pain (Hodges & Richardson, 1996).

Within this framework, the diaphragm has progressively moved from being considered a purely respiratory muscle to being recognized as a key postural and stabilizing structure. Its dual role, sustaining ventilation while simultaneously contributing to the generation of intra-abdominal pressure and lumbar spine stiffness, positions it as a determinant element of the deep stabilization system together with the pelvic floor and transversus abdominis (Kolar et al., 2012). Early experimental work using intramuscular electromyography and ultrasonography demonstrated that the diaphragm contracts tonically in anticipation of postural perturbations, independent of its respiratory rhythm, confirming its dual respiratory-postural function (Hodges et al., 1997). Building on this evidence, subsequent studies have shown that individuals with CNLBP frequently present altered diaphragmatic postural behaviour, including delayed or insufficient descent during anticipatory postural adjustments, along with greater diaphragm fatigability compared with asymptomatic individuals (Janssens et al., 2013). More recent case-control studies using B-mode and M-mode ultrasonography have corroborated these functional differences, reporting a significantly reduced capacity for diaphragmatic thickness change during breathing in individuals with CNLBP relative to healthy controls (Ziaefar et al., 2022).

Building on this pathophysiological rationale, a growing number of randomized controlled trials have tested diaphragm-focused interventions, ranging from manual therapy and myofascial release techniques to inspiratory muscle training and dynamic neuromuscular stabilization exercises. A recent systematic review and meta-analysis pooling seven RCTs concluded that diaphragm-targeted interventions produce large reductions in pain intensity and moderate-to-large improvements in disability, with diaphragmatic training and manual therapy emerging as the most effective modalities, although the overall certainty of evidence was rated as low according to GRADE criteria, largely due to methodological heterogeneity, small sample sizes, and short follow-up periods (Ma et al., 2026; Guyatt et al., 2011). Similar conclusions were reached by manual-therapy specific trials showing that osteopathic protocols incorporating diaphragmatic techniques improve pain and disability more than protocols without a respiratory component (Martí-Salvador et al., 2018), by respiratory-training trials demonstrating that inspiratory

muscle training modifies proprioceptive use of trunk muscles and reduces low back pain recurrence (Janssens et al., 2015), and by trials of manual myofascial release techniques targeting the diaphragm and iliopsoas, which produced significant short-term reductions in pain and disability (Sıgılan & Çolak, 2023).

Notwithstanding this encouraging evidence, several gaps persist. First, most published trials have evaluated isolated techniques (manual therapy or breathing exercises) rather than a combined, protocolized approach that simultaneously addresses the manual, respiratory, and neuromuscular dimensions of diaphragmatic dysfunction. Second, few studies have paired clinical outcome measures with objective diaphragmatic imaging, which limits the mechanistic interpretation of clinical improvements. Third, sample sizes remain modest and group allocation is frequently unbalanced, reducing statistical power and increasing the risk of type II error. Fourth, long-term follow-up beyond three months is rare, despite CNLBP being characterized by a fluctuating and recurrent course. Our research team's own pilot experience with a bilateral cephalad manual diaphragmatic stretching protocol added to conventional physiotherapy (trial registration NCT06069388) illustrated both the clinical promise of this approach, with large effects on pressure pain thresholds and mental-health-related quality of life, and several of these same limitations, including a moderate and unbalanced sample size and the absence of diaphragmatic imaging to substantiate the proposed mechanism of action.

The present chapter proposes a future multicenter, two-phase project designed to directly address these limitations, combining a clinically oriented confirmatory randomized controlled trial with a mechanistic ultrasonographic sub-study, framed within current recommendations for methodological rigor in musculoskeletal rehabilitation research (van Tulder et al., 2003; Page et al., 2021).

Detailed Description of the Project and Objectives

DIAFRAGMA-II is a proposed multicenter, two-phase research project aimed at determining the clinical effectiveness and underlying physiological mechanisms of a multicomponent diaphragm-targeted intervention in adults with CNLBP. Unlike previous single-technique trials, the project integrates three complementary components within a single structured protocol: (1) manual diaphragmatic release and stretching techniques applied bilaterally in cephalad and caudal directions; (2) a progressive inspiratory muscle training programme using calibrated threshold devices; and (3) dynamic neuromuscular stabilization exercises targeting coordinated diaphragmatic-abdominal co-activation during functional tasks.

Phase 1 consists of a confirmatory, adequately powered, multicenter randomized controlled trial comparing the multicomponent diaphragmatic protocol added to conventional physiotherapy against conventional physiotherapy alone, across primary care physiotherapy units of the Andalusian Health Service and university-affiliated outpatient clinics. Phase 2 consists of an embedded mechanistic sub-study conducted in a subsample of participants, in which bilateral diaphragmatic thickness and excursion will be measured by B-mode and M-mode ultrasonography before and after the intervention, allowing the correlation of structural and functional diaphragmatic changes with clinical outcomes.

The intervention is intended for adults aged 18 to 65 years with CNLBP of more than three months' duration and clinical signs of diaphragmatic dysfunction identified through validated screening tests. The project will be implemented over an estimated period of 24 months, including recruitment, intervention, immediate post-intervention assessment, and a 6-month follow-up, thereby addressing the shortage of medium-term outcome data identified in the existing literature.

Project Objectives. Justification of the Interest and Feasibility

General Objective

To design, implement, and evaluate the clinical effectiveness and physiological mechanisms of a multicomponent diaphragm-targeted rehabilitation protocol, compared with conventional physiotherapy

alone, in adults with chronic non-specific low back pain, through a two-phase multicenter randomized controlled trial with 6-month follow-up.

Justification of the Interest and Feasibility of the Project

The scientific interest of DIAFRAGMA-II lies in its capacity to overcome the principal methodological limitations identified in the current evidence base on diaphragm-focused interventions for CNLBP: small and unbalanced samples, single-technique protocols, absence of imaging-based mechanistic verification, and short follow-up periods (Ma et al., 2026). By integrating manual therapy, respiratory training, and neuromuscular stabilization into a single reproducible protocol, and by pairing clinical outcomes with ultrasonographic evidence of diaphragmatic structure and function, the project is positioned to generate higher-certainty evidence capable of informing clinical guidelines.

From a feasibility standpoint, the project builds directly upon the research team's accumulated experience coordinating the DIAFRAGMA pilot trial, including validated assessment protocols for pressure pain thresholds, thoracic mobility, and patient-reported quality of life, as well as established collaboration agreements with primary care physiotherapy units. The multicenter design, distributing recruitment across several primary care and university-affiliated sites, is expected to substantially increase the feasible sample size within a realistic timeframe while preserving ecological validity, since the intervention will be delivered by qualified physiotherapists under routine clinical conditions rather than in a highly controlled laboratory setting.

Finally, the project responds to an explicit call in the most recent systematic review on this topic for future high-quality randomized controlled trials capable of confirming long-term efficacy and standardizing intervention protocols (Ma et al., 2026), positioning DIAFRAGMA-II as a timely and clinically relevant contribution to musculoskeletal rehabilitation research.

Methodology

Description of Materials and Methodology. Planned Activities

DIAFRAGMA-II will adopt a two-arm, parallel-group, assessor-blinded, multicenter randomized controlled trial design (Phase 1), complemented by a nested pre-post mechanistic sub-study using diagnostic ultrasonography (Phase 2). Participants will be recruited from physiotherapy units of the Bahía de Cádiz–La Janda Health District and university-affiliated outpatient clinics, and randomly allocated in a 1:1 ratio to either the experimental group (multicomponent diaphragmatic protocol plus conventional physiotherapy) or the control group (conventional physiotherapy alone), using computer-generated concealed allocation sequences stratified by site and baseline pain intensity.

The experimental protocol will comprise 12 sessions delivered twice weekly over six weeks. Each session will include: (1) 15 minutes of bilateral manual diaphragmatic stretching, combining cephalad and caudal mobilization techniques applied at the costal insertions of the diaphragm; (2) 10 minutes of inspiratory muscle training using a calibrated threshold device set at 30 to 40 percent of each participant's maximal inspiratory pressure, with weekly load adjustment; and (3) 15 minutes of dynamic neuromuscular stabilization exercises progressing from supine diaphragmatic breathing with abdominal co-activation to functional postural tasks in quadruped, kneeling, and standing positions. The control group will receive conventional physiotherapy consisting of lumbopelvic stabilization exercises, stretching, and therapeutic education, matched for session frequency and duration.

Table 1. Eligibility Criteria for Participant Selection

Inclusion criteria	Exclusion criteria
Adults aged 18–65 years	Specific low back pain (fracture, tumour, infection, cauda equina syndrome)
Non-specific low back pain of more than 3 months' duration	Prior lumbar spine surgery
Average pain intensity $\geq 3/10$ on the NPRS during the preceding week	Diagnosed respiratory disease (COPD, asthma exacerbation, restrictive lung disease)
At least one positive clinical sign of diaphragmatic dysfunction (abnormal respiratory pattern, reduced costal excursion, positive diaphragm palpation test)	Pregnancy
Ability to understand and provide written informed consent	Cognitive impairment precluding comprehension of exercise instructions
—	Physiotherapy treatment for low back pain in the preceding 3 months

Table 2. Structured Content of the 12-Session Intervention Protocol (Experimental vs. Control Group)

Component	Experimental group	Control group
Manual therapy	15 min bilateral diaphragmatic stretching (cephalad/caudal)	Not applied
Respiratory training	10 min inspiratory muscle training (threshold device, 30–40% MIP)	Not applied
Neuromuscular stabilization	15 min DNS exercises (supine → quadruped → kneeling → standing)	Not applied
Lumbopelvic stabilization exercise	Embedded within conventional physiotherapy component	20 min lumbopelvic stabilization exercise
General stretching	Embedded within conventional physiotherapy component	10 min general stretching
Therapeutic education	Embedded within conventional physiotherapy component	15 min pain neuroscience education
Frequency and duration	2 sessions/week for 6 weeks (12 sessions, ≈ 40 min)	2 sessions/week for 6 weeks (12 sessions, ≈ 45 min)

Justification of the Methodology According to the Objectives

The proposed methodology is grounded in current biomechanical and neurophysiological evidence indicating that the diaphragm contributes to lumbar spine stability through the generation of intra-abdominal pressure and coordinated co-activation with the transversus abdominis and pelvic floor (Kolar et al., 2012). Combining manual therapy, respiratory training, and neuromuscular stabilization within a single protocol is justified by evidence that each component addresses a distinct dimension of diaphragmatic dysfunction: manual techniques target myofascial restrictions and costal mobility (Sığlan & Çolak, 2023), inspiratory muscle training addresses diaphragmatic fatigability and proprioceptive contribution to postural control (Janssens et al., 2015), and dynamic neuromuscular stabilization exercises retrain the coordinated timing of diaphragmatic-abdominal co-activation during functional movement (Rabieezadeh et al., 2024).

This multicomponent design is therefore aligned with the objective of achieving clinically meaningful and sustained improvements in pain and disability, addressing the mechanistic complexity of diaphragmatic dysfunction more comprehensively than single-technique interventions evaluated in isolation in previous trials.

Suitability of Materials and Methodology to Each Type of Activity

The materials and methodology have been adapted to the different types of activity comprised within the protocol. For the manual therapy component, treating physiotherapists will follow a standardized technique manual with photographic guidance describing hand placement, direction, and progression of diaphragmatic stretching manoeuvres, ensuring inter-therapist consistency across participating centres. For the respiratory training component, calibrated threshold inspiratory muscle trainers will be provided to each participant, together with individualized loading charts and a structured home-practice diary to monitor adherence between supervised sessions. For the neuromuscular stabilization component, a graded

exercise progression card will specify entry criteria for advancing from lower to higher postural demands, ensuring that exercise difficulty is matched to each participant's baseline motor control capacity.

Standardization materials will additionally include a TIDieR-based (Template for Intervention Description and Replication) technique description document, ensuring that the intervention can be reported and replicated in full methodological detail once completed, consistent with recommendations from the Cochrane Back Review Group (van Tulder et al., 2003).

Available Resources and Their Suitability for the Project

The project will be coordinated by the Physiotherapy Department of the Faculty of Nursing and Physiotherapy of the University of Cádiz, in collaboration with the Bahía de Cádiz–La Janda Health District (Andalusian Health Service), the PAIDI CTS-1152 research group, and the Biomedical Research and Innovation Institute of Cádiz (INiBICA). These institutions provide access to outpatient physiotherapy consultation rooms, diagnostic ultrasonography equipment for the mechanistic sub-study, algometry devices for pressure pain threshold assessment, and validated Spanish-language versions of the patient-reported outcome instruments required for the clinical evaluation.

Additional resources include institutional statistical software for the planned intention-to-treat and per-protocol analyses, secure digital case report forms for data management across multiple recruitment sites, and continuing-education sessions to train participating physiotherapists in the standardized delivery of the experimental protocol, ensuring fidelity of implementation across centres.

The project will be conducted in accordance with the ethical principles of the Declaration of Helsinki and will be submitted for approval to the Provincial Research Ethics Committee of Cádiz prior to recruitment. Written informed consent will be obtained from all participants after full explanation of the study procedures, potential risks, and their right to withdraw at any time without consequences for their ongoing clinical care. Personal and clinical data will be pseudonymised at the point of collection and managed in accordance with Spanish Organic Law 3/2018 on Data Protection and Guarantee of Digital Rights and Regulation (EU) 2016/679, with access restricted to the research team through a secure institutional server.

Indicators and Evaluation Procedures

The primary outcome will be change in pain intensity, measured using the Numeric Pain Rating Scale, assessed at baseline, immediately post-intervention, and at 6-month follow-up. Secondary clinical outcomes will include disability (Oswestry Disability Index), pressure pain thresholds at lumbar and paravertebral sites via digital algometry, thoracic and lumbar mobility (cirtometry and modified Schober test), and health-related quality of life using the SF-12 questionnaire, scored into physical and mental component summaries following established methodology (Hagell et al., 2017, as previously applied by the research team).

Mechanistic outcomes, collected in the Phase 2 sub-study, will include diaphragmatic thickness at end-expiration and end-inspiration and diaphragmatic excursion during quiet and deep breathing, measured bilaterally by B-mode and M-mode ultrasonography, allowing calculation of the thickening fraction as an index of contractile diaphragmatic function.

Implementation indicators will include session attendance, home-practice adherence recorded through the training diary, and protocol fidelity, audited through video-recorded sessions rated against the standardized technique manual by an independent assessor blinded to group allocation.

Table 3. Outcome Measures, Instruments and Assessment Time-Points

Domain	Instrument	Baseline	Post-intervention	6-month follow-up
Pain intensity (primary)	Numeric Pain Rating Scale	X	X	X
Disability	Oswestry Disability Index	X	X	X
Pressure pain threshold	Digital algometry (L1–L5, paravertebral)	X	X	X
Thoracic/lumbar mobility	Cirtometry, modified Schober test	X	X	X
Quality of life	SF-12 (PCS/MCS)	X	X	X
Diaphragm thickness/excursion (sub-study)	B-mode/M-mode ultrasonography	X	X	–
Implementation fidelity	Video-rated checklist	–	X	–
Adherence	Home-practice diary	–	X	–

All clinical outcomes will be analysed following the intention-to-treat principle, using linear mixed-effects models with repeated measures, including group, time, and group-by-time interaction as fixed effects, and participant and recruitment site as random effects, to account for the multicenter structure of the data. Per-protocol analyses will be conducted as a sensitivity analysis restricted to participants completing at least 80% of scheduled sessions. Mechanistic outcomes from the ultrasonographic sub-study will be analysed using paired and independent-samples comparisons of pre-post change in diaphragmatic thickening fraction and excursion between groups, followed by correlation analyses between the magnitude of ultrasonographic change and the magnitude of clinical improvement in pain and disability. Statistical significance will be set at $p < .05$, and effect sizes will be reported alongside 95% confidence intervals for all comparisons.

Project Organization and Planning

The project will be organized into five sequential phases over an estimated 24-month period.

Phase 1: Preparation (Months 1–3). Ethical approval, trial registration, standardization of the technique manual, training of participating physiotherapists, and calibration of ultrasonographic assessors.

Phase 2: Recruitment and Baseline Assessment (Months 4–8). Multicenter recruitment across participating physiotherapy units, screening for eligibility, baseline clinical and mechanistic assessments, and randomization.

Phase 3: Intervention Delivery (Months 6–14, overlapping recruitment). Delivery of the 6-week experimental or control protocol to successive recruitment waves, with continuous fidelity monitoring.

Phase 4: Post-Intervention and Follow-up Assessment (Months 9–20). Immediate post-intervention assessments and 6-month follow-up evaluations, conducted by assessors blinded to group allocation.

Phase 5: Analysis and Dissemination (Months 20–24). Statistical analysis following intention-to-treat principles, preparation of manuscripts reporting clinical and mechanistic findings separately, and dissemination of standardized intervention materials to participating clinical sites.

Coordination will be ensured through monthly multicenter monitoring meetings, a shared digital data management platform, and periodic on-site fidelity audits.

Dissemination activities will include the publication of the trial protocol prior to recruitment completion, followed by separate manuscripts reporting clinical and mechanistic findings in peer-reviewed journals indexed in the Journal Citation Reports, in accordance with the CONSORT statement for randomized controlled trials. Results will additionally be presented at national and international physiotherapy and rehabilitation congresses, and a plain-language summary will be provided to participating physiotherapy units to facilitate knowledge transfer into clinical practice.

Results

Expected Results of the Project

Outcomes to Be Evaluated Upon Completion of the Project

The evaluation of DIAFRAGMA-II will focus on determining both the clinical effectiveness of the multicomponent diaphragmatic protocol and the physiological mechanisms underlying observed changes. Primary and secondary clinical outcomes will include pain intensity, disability, pressure pain thresholds, thoracic and lumbar mobility, and health-related quality of life. Mechanistic outcomes will include bilateral diaphragmatic thickness, excursion, and thickening fraction, assessed by ultrasonography.

Implementation outcomes will additionally be evaluated, including protocol fidelity, session attendance, home-practice adherence, and participant-reported acceptability of the multicomponent protocol, allowing conclusions regarding the feasibility of translating the intervention into routine primary care physiotherapy practice.

Description of Evaluation Procedures and Expected Results

Assessments are planned at three time points: baseline, immediately after the 6-week intervention period, and at 6-month follow-up, allowing analysis of both short-term and medium-term effects, an aspect largely absent from previous diaphragm-focused trials (Ma et al., 2026).

Based on the pooled effect sizes reported in the most recent meta-analysis of diaphragmatic interventions for CNLBP (overall pain SMD = -1.11 ; disability SMD = -0.83 ; Ma et al., 2026) and on preliminary findings from the research team's pilot trial showing large effects on pressure pain thresholds, the multicomponent protocol is expected to produce clinically meaningful reductions in pain intensity and disability that are sustained at 6-month follow-up, in contrast to the more limited long-term data available for single-technique interventions.

With regard to quality of life, improvements are expected primarily in the mental health component, consistent with previous findings linking manual diaphragmatic techniques to improvements in psychological well-being domains, while smaller and more variable effects are anticipated for the physical component, in line with the multifactorial nature of physical functioning in CNLBP.

At the mechanistic level, the intervention is expected to produce measurable increases in diaphragmatic thickening fraction and excursion, particularly among participants exhibiting diaphragmatic dysfunction at baseline, providing physiological support for the clinical improvements observed and addressing the current absence of imaging-based confirmation in the diaphragm-CNLBP literature. Correlational analyses are expected to reveal a moderate association between the magnitude of ultrasonographic change and the magnitude of clinical improvement, reinforcing the proposed mechanistic pathway.

Finally, high levels of protocol fidelity, session attendance, and participant acceptability are expected, supporting the feasibility of implementing the multicomponent protocol within routine primary care physiotherapy services beyond the research context.

Several limitations are anticipated. First, blinding of treating physiotherapists to group allocation is not feasible given the manual and exercise-based nature of the intervention, although outcome assessors and data analysts will remain blinded throughout the study. Second, the multicenter design, while increasing feasible sample size and ecological validity, may introduce between-site variability in intervention delivery despite standardization efforts, which will be monitored through fidelity audits. Third, the mechanistic ultrasonographic sub-study will be restricted to a subsample of participants for feasibility reasons, which may limit the statistical power of correlational analyses between structural and clinical change.

Conclusions

Conclusions. Innovations Derived from the Implementation of the Project

The DIAFRAGMA-II project represents a methodologically robust response to the principal limitations identified in the current evidence on diaphragm-targeted interventions for chronic non-specific low back pain. By integrating manual therapy, inspiratory muscle training, and dynamic neuromuscular stabilization within a single standardized protocol, the project moves beyond the single-technique trials that have characterized this field to date, offering a more comprehensive test of the diaphragm's contribution to lumbopelvic stability.

A central innovation of the project lies in its two-phase design, which pairs a confirmatory multicenter randomized controlled trial with a nested mechanistic ultrasonographic sub-study, enabling direct correlation between structural and functional diaphragmatic changes and clinical outcomes. This combination directly addresses the recurrent criticism, present throughout the diaphragm-CNLBP literature, that clinical improvements following diaphragm-focused interventions lack physiological verification (Ma et al., 2026).

The project also introduces methodological improvements over previous trials in this domain, including an adequately powered multicenter sample, balanced randomization, extended 6-month follow-up, and a fully standardized, TIDieR-reported intervention protocol, thereby responding to explicit calls in the literature for higher-certainty evidence and standardized protocols (Ma et al., 2026; van Tulder et al., 2003).

From a translational perspective, the project has been designed for implementation within existing primary care physiotherapy structures, using equipment and techniques already familiar to qualified physiotherapists, which is expected to facilitate future scalability within the Andalusian Health Service and other public health systems. If the expected outcomes are confirmed, DIAFRAGMA-II has the potential to provide higher-certainty evidence supporting the inclusion of standardized diaphragm-targeted protocols within clinical guidelines for chronic non-specific low back pain, while advancing understanding of the biomechanical pathways linking respiratory and lumbopelvic function.

References

- Chiarotto, A. & Koes, B. W. (2022). Nonspecific low back pain. *New England Journal of Medicine*, 386(18), 1732–1740. <https://doi.org/10.1056/NEJMc2032396>
- Revisar autores Guyatt, G. H., Oxman, A. D., Kunz, R., Brozek, J., Alonso-Coello, P., Rind, D., Devereaux, P. J., Elbourne, D., Jaeschke, R., Vist, G., Schünemann, H. J., & GRADE Working Group. (2011). GRADE guidelines: 6. Rating the quality of evidence—imprecision. *Journal of Clinical Epidemiology*, 64(12), 1283–1293. <https://doi.org/10.1016/j.jclinepi.2011.01.012>
- Inyoung, K. (2024). The effect of the diaphragm stretching technique in the diaphragm contraction rate and trunk muscle activity in back pain patients. *Journal of Back and Musculoskeletal Rehabilitation*, 37(1), 225–231. <https://doi.org/10.3233/BMR-230141>
- Janssens, L., Brumagne, S., McConnell, A. K., Claeys, K., & Pijnenburg, M. (2013). Greater diaphragm fatigability in individuals with recurrent low back pain. *Respiratory Physiology & Neurobiology*, 188(2), 119–123. <https://doi.org/10.1016/j.resp.2013.05.028>
- Janssens, L., McConnell, A. K., Pijnenburg, M., Claeys, K., Goossens, N., Lysens, R., Troosters, T., & Brumagne, S. (2015). Inspiratory muscle training affects proprioceptive use and low back pain. *Medicine & Science in Sports & Exercise*, 47(1), 12–19. <https://doi.org/10.1249/MSS.0000000000000385>
- Kolar, P., Sulc, J., Kyncl, M., Sanda, J., Cakrt, O., Andel, R., Kumagai, K., & Kobesova, A. (2012). Postural function of the diaphragm in persons with and without chronic low back pain. *Journal of Orthopaedic & Sports Physical Therapy*, 42(4), 352–362. <https://doi.org/10.2519/jospt.2012.3830>
- Ma, B., Xiangli, J., Shi, H., & Liu, X. (2026). Diaphragmatic dysfunction and activation interventions for chronic nonspecific low back pain: A systematic review and meta-analysis. *Journal of Back and Musculoskeletal Rehabilitation*, 39(4), 1340–1354. <https://doi.org/10.1177/10538127261418331>

- Martí-Salvador, M., Hidalgo-Moreno, L., Doménech-Fernández, J., Lisón, J. F., & Arguisuelas, M. D. (2018). Osteopathic manipulative treatment including specific diaphragm techniques improves pain and disability in chronic nonspecific low back pain: A randomized trial. *Archives of Physical Medicine and Rehabilitation*, 99(9), 1720–1729. <https://doi.org/10.1016/j.apmr.2018.04.022>
- Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., Brennan, S. E., Chou, R., Glanville, J., Grimshaw, J. M., Hróbjartsson, A., Lalu, M. M., Li, T., Loder, E. W., Mayo-Wilson, E., McDonald, S., McGuinness, L. A., ... Moher, D. (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ (Clinical research ed.)*, 372, n71. <https://doi.org/10.1136/bmj.n71>
- Rabieezadeh, A., Mahdavejad, R., Sedehi, M., & Adimi, M. (2024). The effects of an 8-week dynamic neuromuscular stabilization exercise on pain, functional disability, and quality of life in individuals with non-specific chronic low back pain: a randomized clinical trial with a two-month follow-up study. *BMC Sports Science, Medicine & Rehabilitation*, 16, Artículo 161. <https://doi.org/10.1186/s13102-024-00948-9>
- Sığlan, Ü. & Çolak, S. (2023). Effects of diaphragmatic and iliopsoas myofascial release in patients with chronic low back pain: A randomized controlled study. *Journal of Bodywork and Movement Therapies*, 33, 120–127. <https://doi.org/10.1016/j.jbmt.2022.09.029>
- Van Tulder, M., Furlan, A., Bombardier, C., & Bouter, L. (2003). Updated method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group. *Spine*, 28(12), 1290–1299. <https://doi.org/10.1097/01.BRS.0000065484.95996.AF>
- Vicente-Campos, D., Sanchez-Jorge, S., Terrón-Manrique, P., Guisard, M., Collin, M., Castaño, B., Rodríguez-Sanz, D., Becerro-de-Bengoa-Vallejo, R., Chicharro, J. L., & Calvo-Lobo, C. (2021). The Main Role of Diaphragm Muscle as a Mechanism of Hypopressive Abdominal Gymnastics to Improve Non-Specific Chronic Low Back Pain: A Randomized Controlled Trial. *Journal of Clinical Medicine*, 10(21), 4983. <https://doi.org/10.3390/jcm10214983>
- Masroor, S., Tanwar, T., Aldabbas, M., Iram, I., & Veqar, Z. (2023). Effect of Adding Diaphragmatic Breathing Exercises to Core Stabilization Exercises on Pain, Muscle Activity, Disability, and Sleep Quality in Patients With Chronic Low Back Pain: A Randomized Control Trial. *Journal of Chiropractic Medicine*, 22(4), 275–283. <https://doi.org/10.1016/j.jcm.2023.07.001>
- GBD 2021 Low Back Pain Collaborators (2023). Global, regional, and national burden of low back pain, 1990–2020, its attributable risk factors, and projections to 2050: a systematic analysis of the Global Burden of Disease Study 2021. *The Lancet. Rheumatology*, 5(6), e316–e329. [https://doi.org/10.1016/S2665-9913\(23\)00098-X](https://doi.org/10.1016/S2665-9913(23)00098-X)
- Hodges, P. W., Butler, J. E., McKenzie, D. K., & Gandevia, S. C. (1997). Contraction of the human diaphragm during rapid postural adjustments. *The Journal of Physiology*, 505(2), 539–548. <https://doi.org/10.1111/j.1469-7793.1997.539bb.x>
- Hodges, P. W. & Richardson, C. A. (1996). Inefficient muscular stabilization of the lumbar spine associated with low back pain. A motor control evaluation of transversus abdominis. *Spine*, 21(22), 2640–2650. <https://doi.org/10.1097/00007632-199611150-00014>
- Ziaefar, M., Sarrafzadeh, J., Noorizadeh Dehkordi, S., Arab, A. M., Haghighatkah, H., & Zendehele Jadehkenari, A. (2022). Diaphragm thickness, thickness change, and excursion in subjects with and without nonspecific low back pain using B-mode and M-mode ultrasonography. *Physiotherapy Theory and Practice*, 38(13), 2441–2451. <https://doi.org/10.1080/09593985.2021.1926022>