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EUROPEAN KNOWLEDGE ALLIANCE FOR INNOVATIVE MEASURES IN PREVENTION OF WORK-RELATED MUSCULOSKELETAL PAIN DISORDERS (PREVENT4WORK PROJECT): PROTOCOL FOR AN INTERNATIONAL MIXED METHODS LONGITUDINAL STUDY

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ABSTRACT

Introduction

Work-related musculoskeletal (MSK) pain is a highly prevalent condition and one of the main contributors to disability and loss of work capacity. Current approaches for the management and prevention of work-related MSK pain do not integrate current evidence-based knowledge and seem to be outdated. The Prevent4Work (P4W) project aims to collect and spread evidence-based information to improve the management and prevention of work-related MSK pain. P4W will longitudinally investigate i) risk factors associated with the prevalence of work-related MSK pain, ii) predictive factors for new events of work-related MSK pain in the short term, and iii) the modification of pain beliefs after participating in evidence-based e-learning courses.

Methods and analysis

This project employs a mixed-methods design with international cohorts of workers from Spain, Italy, and Denmark. All participants will be assessed using self-reported variables at baseline (i.e., cross-sectional design) with follow-up after 3 and 6-months (i.e., prospective-predictive design). Throughout the first phase (month 0-3), all participants will be offered to self-enroll in e-learning courses on work-related MSK pain. Changes in pain beliefs (if any) will be assessed (i.e., pragmatic design). The dataset will include sociodemographic characteristics, physical and psychological job demands, lifestylerelated factors, MSK pain history, and pain beliefs. At baseline all participants will additionally complete the P4W questionnaire developed to detect populations at high risk of suffering work-related MSK pain.

Descriptive statistics, binary logistic regression, and analysis of variance will be used to identify the significant factors that influence the history of work-related MSK pain, evaluate the short-term prediction capacity of the P4W questionnaire, and investigate if workers' participation in e-learning courses modify their pain beliefs.

Ethics and dissemination

The study received ethical approval from the Ethical Committee of San Jorge University (USJ011-19/20). The results will be made available via peer-reviewed publications, international conferences and Prevent4Work official channels.

ARTICLE SUMMARY

Strengths and limitations of this study

- Large international longitudinal study examining risk factors associated with the prevalence and the incidence of work-related MSK pain.
- Prospective evaluation of workers' participation in e-learning evidence-based courses and its effect on pain beliefs and work-related MSK pain.
- Multidimensional assessment of workers is conducted.
- Only self-reported variables are obtained.

Key Words:

Occupational & Industrial medicine, Musculoskeletal Disorders, Pain Management.

INTRODUCTION

Work-related musculoskeletal (MSK) pain refers to pain related to or leading to workrelated disability.¹ The level of disability can range from low to high and be episodic or permanent, thus reducing workers' quality of life and work capacity.² Self-reported pain in the neck and low back is the main complaint of workers reporting interfering pain.³ According to the Sixth European Working Conditions Survey, 40% of workers report one event of pain per year, while 20% report having a chronic pain condition.⁴

Work-related MSK pain is a complex condition, consisting of multiple interacting factors such as i) physical factors (e.g., manual handling, working in awkward postures, repetitive work, and working at high speed), ii) individual factors (e.g., stress exposure, health believes, beliefs about pain, sleep quality, social support), iii) contextual factors (e.g., workplace design and organization) and, iv) sociodemographic factors (e.g., level of education).⁵

The incidence and prevalence rates of work-related MSK pain are increasing world-wide, which may indicate a sub-optimal effect of contemporary approaches for its management.⁶ Insufficient implementation of evidence-based practice might be the primary contributor,⁷ although outdated education of health care professionals and low-value treatments are also barriers for optimal management of work-related MSK pain.⁸⁹

Previous, large-scale initiatives have demonstrated that educational interventions can modify pain beliefs among workers.¹⁰ Therefore, given that outdated beliefs and expectations about health are associated with a higher risk of work-related MSK pain¹¹ and potentially with chronicity and disability,¹² educational interventions could be an ideal starting point. However, the impact of changes in pain beliefs on reducing new events and/or chronicity of work-related MSK pain has not yet been investigated.

Prevent4Work project:

The European Knowledge Alliance "Prevent4Work" (P4W) project focuses on highquality education for professionals and laypeople with regards to work-related MSK pain. This initiative has been created to improve work-related MSK pain management strategies by developing and implementing new assessment and interactive digital platforms. A self-perceived risk assessment questionnaire (P4W questionnaire) has recently been developed to detect populations at high risk of suffering work-related MSK pain.¹³ Moreover, innovative educational programs will be introduced, and adaptive mobile interactive digital platforms, capable of delivering evidence-based information and collect data will be continuously developed (Supplemental Table 1).

The research-specific aims of the P4W project are i) to identify risk factors associated with the prevalence and/or the incidence of work-related MSK pain, ii) to evaluate the predictive capacity of the P4W questionnaire for new events of work-related MSK pain in the short term (i.e., three and six months), iii) to evaluate whether pain beliefs are modified in the short term after participating in e-learning evidence-based training activities about work-related MSK pain.

It has been suggested that the pandemic situation related to COVID-19 has had a significant negative effect on the physical and mental wellbeing of people with chronic pain.¹⁴ Additionally, there is insufficient data on how/if the pandemic causes new events or flare-ups of pain across the successive waves of contagion.¹⁵ Therefore, the project will explore potential relationships with the development of new events of self-perceived work-related MSK pain.

METHODS

The present study protocol has complies with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations.¹⁶

Study design

This study protocol will follow a longitudinal mixed-methods design with international cohorts. All participants will be assessed by using self-reported variables at baseline (i.e., cross-sectional study design) and at 3 and 6-month follow-ups (i.e., prospective-predictive study design). Throughout the first phase (month 0-3), all participants will be offered to self-enroll in a free-learning course about work-related MSK pain. The analysis of data will be performed following a pragmatic study design (see figure 1).

FIGURE 1 HERE

Population

The cohort will be composed of people in employment between 18 and 65 years of age, from Denmark, Italy, and Spain, who are fluent in either English, Danish, Italian, or Spanish, who have an easy access to a tablet/smartphone and internet. No specific exclusion criteria will be considered to be enrolled in the study. In the event of an enrolled participant changing the initial job position or taking any sort of leave during the study period, he/she will be excluded from the follow-up analysis.

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Contact and recruitment

Companies, institutions, and workers associations from Denmark, Italy, and Spain are invited to participate in P4W actions via the P4W network. Each organization will provide their workers information in the local language together with two animated videos (also in the local language) explaining the aims and actions of the P4W project. The participants recruited through here will provide data that will enable an evaluation of risk factors associated with work-related MSK pain. Likewise, their participation in the P4W e-learning courses about work-related MSK pain will allow for an evaluation of the content from a user perspective. Participating organizations will be assigned a national liaison for first-line support.

Data collection and security measures

Data collection will be conducted between April and December 2021. When registering in the application for mobile devices (app), participants will have to accept the informed consent to before they get a personal account. Two reminder messages will appear within the main panel of the app. The first one will indicate that the linking with the responsible academic institution in their country of residence is pending execution, while the second one will remind that the survey and P4W questionnaire is ready to be completed.

All personal and survey data will be stored with record-level encryption at the database level, meaning that it is all incomprehensible without first being decrypted. Besides, the survey data will be pseudo-anonymized, so it is impossible to relate the physical person and with their data directly. For processing and exporting purposes, all data will be conveniently anonymized in a way that each data record is generated with a unique identifier that is not possible to relate with the physical person and its personal information.

All the measures have been conducted to comply with EU's General Data Protection Regulation ¹⁷ and implemented following recommended guidelines.^{18 19}

P4W courses

All participants will be informed that they can choose to participate in one or more elearning courses. P4W study group published a scoping review on the role of education in preventing and treating work-related MSK pain, finding that there is a basis for using education to complement other treatments.¹ Here, they can access animated videos with essential messages from systematic reviews on work-related MSK pain which have been produced specifically in relation to the project (Supplemental Table 2). The videos were developed in English and Spanish languages, with Italian or Danish subtitles and are publicly available in <u>https://p4work.com/results/</u> (retrieved on 31st March 2021). For further analysis, all participants that have been invited to take the courses will be classified based to their interaction with the animated videos as: i) No participation at all, ii) Visualization of videos in isolation / Starting, but not finishing an e-learning course, iii) Completion of one or more entire learning courses.

Outcome measures

Table 1 summarizes outcome domains over the length of the study. Specific outcomes measures are presented in detail afterward.

Table 1. Summary of outcome domains assessed over the length of the study,

 including risk factors potentially associated with prevalence and/or incidence

 of work-related MSK pain.

Period	Domains
	• P4W survey
	 Individual factors
• Baseline	 Job demands
	o Lifestyle
	• MSK pain history

	o COVID-19
	• Pain Beliefs
	• Work-related MSK pain training
	experience and interests
	• P4W questionnaire
	• P4W follow-up survey
	\circ Verification of same job position
	• Verification of e-learning course
• 3- and 6-month follow-up	participation
• 5 and 6 month follow up	∘ Lifestyle
	 MSK pain history
	• COVID-19
	• Pain Beliefs

<u>Baseline</u>

At baseline, all participants will complete a survey composed of 5 sections:

<u>Section 1</u>: This section will collect sociodemographic and personal information such as age, sex, weight, height, education level, job position and seniority.

<u>Section 2</u>: This section will collect information about job demands at different levels such as physical demand, psychological demand, and decision capacity. Each domain is composed of different questions assessed on a 5-item Likert scale. The average scores of the different questions in each domain are classified as being in "high demand", "medium demand" or "low demand".²⁰ Following the same structure, four additional categories will be assessed in the P4W survey: "maintained postures", "repetitive movement", "overstrain", and "overtime".

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<u>Section 3</u>: This section will collect information about lifestyle (physical activity out of work, sleep quality and quantity), medical history of MSK pain (including onset e.g., whiplash injury due to a car accident) and COVID-19 impact.

- **Physical activity** in leisure time will be evaluated by using the Global Physical Activity Questionnaire²¹ proposed by the World Health Organization. Participants will be asked to indicate the number of days (if any) in a typical week and the average time in a day (in hours and minutes) they spend doing such type of moderate or vigorous intensity activities.
- Sleep quality will be evaluated by using the Medical Outcomes Study Sleep Scale.²² Specifically, the sleep adequacy domain, composed of only 2 questions, will be assessed. This domain is rated on a 6-item Likert scale, and the average of the two questions is transformed to a percentage. Sleep quantity will be assessed by asking for the average number of hours slept per night during the last 4 weeks.
- Prevalence and history of self-reported work-related MSK pain will be evaluated using the extended version of the Nordic Musculoskeletal Questionnaire.²³ The original 9 body regions in the original scale will be reduced to 4 (neck pain, low back pain, upper limb pain and lower limb pain). As part of the extended version, medication consumption, use of health services (physiotherapist, doctor, etc.) and difficulties to carry out work tasks, will be registered to evaluate the impact of MSK pain in workers.
- **COVID-19 impact** will be explored as a potential contributor to developing or aggravating MSK pain¹⁵ by using supplementary ad hoc questions.

<u>Section 4</u>: Information about beliefs related to the cause and treatment of pain are collected using the Pain Beliefs Questionnaire.²⁴ The Pain Beliefs Questionnaire is a

12-item questionnaire with a 6-point Likert scale that taps into the two dimensions of pain beliefs (organic and psychological beliefs).

<u>Section 5</u>: This section will collect information about the participants' training experience and interests in the field of work-related MSK pain. The different topics are based on the current management of work-related MSK pain and the latest evidence regarding factors and interventions that can contribute to increase or decrease the risk of suffering work-related MSK pain.⁵

<u>Prevent4Work Questionnaire</u>: All workers will complete the P4W questionnaire. This self-perceived risk assessment questionnaire was developed to detect populations at high risk of work-related MSK pain.¹³ The instrument uses a biopsychosocial approach based on 20 items with a 5-point Likert scale and investigates four different domains: Physical Stress, Mental Stress, Job Satisfaction and Kinesiophobia.

Follow-up at 3 and 6 months

 At follow-up (3 and 6-months), all participants will receive a reduced version of the survey conducted at baseline. This reduced version of the survey will be composed of i) a specific question to assure the participant is performing the same job and type of work as baseline level, ii) a specific self-reported question related to the participation in e-learning courses, iii) a reduced version of the Nordic Musculoskeletal Questionnaire regarding the experience of new events of self-reported MSK pain in the last 3-6 months, and iv) the Pain Beliefs Questionnaire.

Data from the 3-month follow-up will be used to evaluate any potential change in pain beliefs, whilst 6-month follow-up will be used to test the short-term prediction

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capacity of the P4W questionnaire for new events of MSK pain within the cohort of workers at the neck, low back, upper limb, or lower limb.

Sample size

The present large-scale project needs to reach a sample of 1.500 workers to meet the European Commission requirements and analyze the current risk factors for MSK pain. This sample size is estimated to be valid to test the short-term prediction capacity of P4W questionnaire for a new event of self-reported MSK pain based on performing a binary logistic regression.²⁵ Under these circumstances, at least 331 workers should be followed-up at 6 months in order to evaluate the predictive capacity of 10 candidate variables with an incidence expectation at $15\pm5\%$ of a new episode of self-reported MSK pain.^{26 27} Additionally, the sample size will be large enough (n>158) to detect small to medium differences within workers in the Pain Beliefs Questionnaire (Cohen's effect size d= $0.26)^{28}$ with an alfa error of 0.05 and a power of 90%.

Statistical analysis

In relation to the first aim, linked to the cross-sectional study, multiclass or binary logistic regression will be applied to identify the major factors that influence the presence and/or recent history of work-related MSK pain. In relation to the second aim, linked to the cohort study, binary logistic regression will be used to evaluate the short-term prediction capacity of the P4W questionnaire with regards to the appearance of a new MSK pain event in the past 6 months according to the Nordic Musculoskeletal Questionnaire. In relation to the third aim, linked to the pragmatic study, repeated measures analysis of variance will be used to determine if workers' participation in e-learning courses modify their pain beliefs. The analysis will be conducted under the intention-to-treat and perprotocol principles, and the effect sizes will be reported for a better interpretation and

controlling the risk of type-1 error. The significance level will be established for all the analyses at P<0.05.

Ethics and confidentiality

The study protocol was approved by the ethical committee at San Jorge University (USJ011-19/20). Each participant will be automatically assigned a study code once they register on the app. This code will be the only downloadable information together with health data by study researchers. All personal data needed for registration will be saved in an independent database, which will be only accessible only for the principal investigator and study coordinators in each country. Any deviation from the current protocol will be explained and justified if necessary.

Dissemination

The results, regardless of the outcome, will be made available via peer-reviewed publications in open-source journals, relevant international conferences in the field of pain and occupational health, and via P4W official channels, such as the P4W website, social media channels, and final project symposium. Results will likewise be done by producing new high-quality videos on the P4W YouTube channel.

REFERENCES

- Palsson TS, Boudreau S, Høgh M, et al. Education as a strategy for managing occupational-related musculoskeletal pain: a scoping review. *BMJ Open* 2020;10(2):e032668.
- Chang YF, Yeh CM, Huang SL, et al. Work Ability and Quality of Life in Patients with Work-Related Musculoskeletal Disorders. *Int J Environ Res Public Health* 2020;17(9)
- 3. de Kok J, Vroonhof P, Snijders J, et al. Work-related musculoskeletal disorders: prevalence, costs and demographics in the EU. Luxembourg: European Agency for Safety and Health at Work 2019. Available: https://osha.europa.eu/sites/default/files/publications/documents/Workrelated_MSDs_prevalence_costs_and_demographics_in_the_EU_report.pdf
- 4. Parent-Thirion A, Biletta I, Cabrita J, et al. Sixth European Working Conditions Survey

 Overview report (2017 update). Luxembourg: European Foundation for the
 Improvement of Living and Working Conditions 2017. Available:
 https://www.eurofound.europa.eu/sites/default/files/ef_publication/field_ef_doc
 ument/ef1634en.pdf
- 5. Isusi I. Work-related musculoskeletal disorders Facts and figures. Luxembourg: European Agency for Safety and Health at Work 2020. Available: https://osha.europa.eu/sites/default/files/publications/documents/Work_related_ musculoskeletal disorders %20Facts and figures.pdf
- 6. Crawford JO, Davis A. Work-related musculoskeletal disorders: why are they still so prevalent? Evidence from a literature review. Luxembourg: European Agency for Safety and Health at Work 2020. Available: https://osha.europa.eu/sites/default/files/publications/documents/Work_related_ musculoskeletal disorders why so prevalent report.pdf

- Buchbinder R, Underwood M, Hartvigsen J, et al. The Lancet Series call to action to reduce low value care for low back pain: an update. *Pain* 2020;161 Suppl 1(1):S57-S64.
- Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet* 2018;**391**(10137):2368-83.
- Slade SC, Kent P, Patel S, et al. Barriers to Primary Care Clinician Adherence to Clinical Guidelines for the Management of Low Back Pain: A Systematic Review and Metasynthesis of Qualitative Studies. *Clin J Pain* 2016;**32**(9):800-16.
- Andersen LL, Geisle N, Knudsen B. Can beliefs about musculoskeletal pain and work be changed at the national level? Prospective evaluation of the Danish national Job & Body campaign. *Scand J Work Environ Health* 2018;44(1):25-36.
- Vargas-Prada S, Coggon D. Psychological and psychosocial determinants of musculoskeletal pain and associated disability. *Best Pract Res Clin Rheumatol* 2015;29(3):374-90.
- 12. Coggon D, Ntani G, Palmer KT, et al. Disabling musculoskeletal pain in working populations: is it the job, the person, or the culture? *Pain* 2013;**154**(6):856-63.
- Langella F, Christensen SWM, Palsson TS, et al. Development of the Prevent for Work questionnaire (P4Wq) for assessment of musculoskeletal risk in the workplace: part 1-literature review and domains selection. *BMJ Open* 2021;11(4):e043800.
- Carrillo-de-la-Peña MT, González-Villar A, Triñanes Y. Effects of the COVID-19 pandemic on chronic pain in Spain: a scoping review. *Pain Rep* 2021;6(1):e899.
- 15. Cipollaro L, Giordano L, Padulo J, et al. Musculoskeletal symptoms in SARS-CoV-2 (COVID-19) patients. *J Orthop Surg Res* 2020;15(1):178.

- 16. von Elm E, Altman DG, Egger M, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;**335**(7624):806-8.
- 17. 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 repealing Directive 95/46/EC (General Data Protection Regulation). *Official Journal of the European Union* 2016;**119**(1)
- 18. Agencia Española de Protección de Datos A. Orientaciones y garantías en los procedimientos de anonimización de datos personales. 2016. Available: https://www.aepd.es/sites/default/files/2019-09/guia-orientacionesprocedimientos-anonimizacion.pdf
- 19. Agencia Española de Protección de Datos A. Guía del Reglamento General de Protección de Datos para responsables de tratamiento. 2016. Available: https://www.aepd.es/sites/default/files/2019-09/guia-rgpd-para-responsables-detratamiento.pdf
- 20. Cantley LF, Tessier-Sherman B, Slade MD, et al. Expert ratings of job demand and job control as predictors of injury and musculoskeletal disorder risk in a manufacturing cohort. *Occup Environ Med* 2016;**73**(4):229-36.
- 21. Wanner M, Hartmann C, Pestoni G, et al. Validation of the Global Physical Activity Questionnaire for self-administration in a European context. *BMJ Open Sport Exerc Med* 2017;3(1):e000206.
- 22. Hays RD, Martin SA, Sesti AM, et al. Psychometric properties of the Medical Outcomes Study Sleep measure. *Sleep medicine* 2005;**6**(1):41-4.
- 23. Dawson AP, Steele EJ, Hodges PW, et al. Development and test-retest reliability of an extended version of the Nordic Musculoskeletal Questionnaire (NMQ-E): a

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screening instrument for musculoskeletal pain. *The journal of pain : official journal of the American Pain Society* 2009;**10**(5):517-26.

- 24. Edwards LC, Pearce SA, Turner-Stokes L, et al. The Pain Beliefs Questionnaire: an investigation of beliefs in the causes and consequences of pain. *Pain* 1992;**51**(3):267-72.
- Riley RD, Ensor J, Snell KIE, et al. Calculating the sample size required for developing a clinical prediction model. *BMJ* 2020;368:m441.
- 26. Ostergren PO, Hanson BS, Balogh I, et al. Incidence of shoulder and neck pain in a working population: effect modification between mechanical and psychosocial exposures at work? Results from a one year follow up of the Malmö shoulder and neck study cohort. *J Epidemiol Community Health* 2005;**59**(9):721-8.
- 27. Vargas-Prada S, Serra C, Martínez JM, et al. Psychological and culturally-influenced risk factors for the incidence and persistence of low back pain and associated disability in Spanish workers: findings from the CUPID study. *Occup Environ Med* 2013;**70**(1):57-62.
- 28. Baird AJ, Haslam RA. Exploring differences in pain beliefs within and between a large nonclinical (workplace) population and a clinical (chronic low back pain) population using the pain beliefs questionnaire. *Phys Ther* 2013;**93**(12):1615-24.

DECLARATIONS

Authors' contributions

All authors contributed significantly to the design of this study protocol and lived up to the requirements of the International Committee of Medical Journal Editors (ICMJE). PBL, VDG, TSP, SWMC, PS, FL, PB, PH and MH contributed to the conception and planning of the study protocol. PBL, VDG, TSP, PS, AR, PB and MH contributed to the acquisition of the data for the work. PBL, VDG, TSP, SWMC, PS, PSJ, FL, PB, AB, JBA, CJS, SC, DJC, PH and MH contributed to the development of educational content and evaluation tools. All authors contributed to writing the article and have read and approved the final manuscript.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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Supplemental table 1. List of P4W links resources: innovative educational programs and adaptive mobile interactive digital platforms for delivering evidence-based information and collecting data.

Resource	Link
P4W web page	https://p4work.com/
P4W app for iOS	https://apps.apple.com/es/app/p4work/id1 509417286
P4W app for Android	https://play.google.com/store/apps/details ?id=com.geoslab.p4w&hl=es
P4W e-learning platform	https://aulaonline.p4work.com/
P4W Youtube channel	https://www.youtube.com/channel/Preve nt4Work
P4W Facebook account	https://www.facebook.com/Prevent4Wor k-558730587928229/
P4W Linkedin profile	https://www.linkedin.com/company/prev ent4work/
P4W video presentation	https://youtu.be/PNcVgohx1jw
P4W app videotutorial	https://youtu.be/M6mDbN6itIw
P4W e-learning platform videotutorial	https://youtu.be/S0ORsO0ECZk

Supplemental table 2. List of P4W animated educational videos with essential messages

and evidence-based information related to musculoskeletal pain and work.

# Video & Link	Title	Description	Inspired in the article
1 https://youtu.be /7cao2oIyomg	P4Work Best Practices for Musculoskeletal Pain management (1): Patient- Centred Care	This is the first of three videos where you will learn about the best recommendations for addressing musculoskeletal pain in your clinical practice. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan;54(2):79-86.
2 https://youtu.be /3qBWsV_v2n M	P4Work Best Practices for Musculoskeletal Pain management (2): Clinical Screening	This is the second of three videos where you will learn about the best recommendations for addressing musculoskeletal pain in your clinical practice. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan:54(2):79-86.
3 https://youtu.be /wxlOG1yRVS g	P4Work Best Practices for Musculoskeletal Pain management (3): Interventions and Recommendations	This is the third of three videos where you will learn about the best recommendations for addressing musculoskeletal pain in your clinical practice. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan;54(2):79-86.

# Video & Link	Title	Description	Inspired in the article
4 <u>https://youtu.be</u> <u>/k1CAyUDr1x</u> <u>I</u>	P4Work Recommendations for people suffering from Musculoskeletal Pain	In this video you will learn about the best and updated recommendations for people having musculoskeletal pain. This video is intended for a public audience who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan:54(2):79-86
5 https://youtu.be /Bad9Wjb0hU U	P4Work Best scientific evidence on self- management programs for chronic low back pain	This video you will learn about the importance of the self-management program for chronic low back pain. It wants to teach people how to manage their pain and better-known related care decisions. This video is intended for a public audience who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan;54(2):79-86 Du S, Hu L, Dong J, Xu G, Chen X, Jin S, Zhang H, Yin H. Self- management program for chronic low back pain: A systematic review and meta- analysis. Patient Educ Couns. 2017 Jan:100(1):37.49

# Video & Link	Title	Description	Inspired in the article
6	P4Work What	In this video you will	Hartvigsen J, Hancock
	everyone should	learn about the concept	MJ, Kongsted A, Louw
https://youtu.be	know about low	of "Low Back Pain" and	Q, Ferreira ML,
/9De7xeDATG	back pain	related issues such as	Genevay S, Hoy D,
U	1	prevalence, prognosis,	Karppinen J, Pransky
—		and evidence-based recommendations for its	G, Sieper J, Smeets RJ, Underwood M; Lancet
		management.	Low Back Pain Series Working Group. What
		This video is intended for	low back pain is and
		a public audience who	why we need to pay
		want to learn more about	attention. Lancet. 2018
		the topic.	Jun
			9;391(10137):2356- 2367.
	0		Foster NE, Anema JR,
			Cherkin D, Chou R,
			Cohen SP, Gross DP,
			Ferreira PH, Fritz JM,
			Koes BW, Peul W,
		~	Turner JA, Maher CG;
			Lancet Low Back Pain
			Series Working Group.
		6.	Prevention and
			treatment of low back
			pain: evidence,
			challenges, and
		7	promising directions.
			Lancet. 2018 Jun
			9;391(10137):2368-
			2383.
7	P4Work	In this video you will	Hayden JA, Wilson
	Recovery	learn more about how	MN, Riley RD, Iles R,
https://youtu.be	expectations and	positive or negative	Pincus T, Ogilvie R.
/aGEKmT81S-	prognosis in Low	expectations might	Individual recovery
A	Back Pain	influence return to work	expectations and
		after a low back pain	prognosis of outcomes
		episode.	in non-specific low
			back pain: prognostic
		This video is intended for	factor review.
		a public audience who	Cochrane Database
		want to learn more about	Syst Rev. 2019 Nov
		the topic.	25;2019(11):CD01128

# Video & Link	Title	Description	Inspired in the article
8 https://youtu.be /BVJy3DxUR L0	P4Work Workplace interventions to prevent work disability in workers on sick leave	In this video you will learn about the possible workplace interventions that can be conducted to prevent work disability in workers on sick leave. This video is intended for a general audience who wants to learn more about the topic. However, it is mainly meant for health professionals and persons responsible for occupational safety and health in businesses, companies, and	van Vilsteren M, van Oostrom SH, de Vet HC, Franche RL, Boot CR, Anema JR. Workplace interventions to prevent work disability in workers on sick leave. Cochrane Database Syst Rev. 2015 Oct 5;(10):CD006955.
9 https://youtu.be /j3Sh7AbdWV M	P4Work Workplace interventions to reduce musculoskeletal pain in physically demanding jobs	institutions. In this video you will learn about workplace interventions to rehabilitate musculoskeletal disorders among employees with physically demanding work. It is about interventions and attitudes to be taken in the workplace to improve musculoskeletal pain management and to prevent injuries. This video is intended for a general audience who wants to learn more about the topic. However, it is mainly meant for health professionals and persons responsible for occupational safety and health in businesses, companies, and institutions	Sundstrup E, Seeberg KGV, Bengtsen E, Andersen LL. A Systematic Review of Workplace Interventions to Rehabilitate Musculoskeletal Disorders Among Employees with Physical Demanding Work. J Occup Rehabil. 2020 Dec;30(4):588-612.

# Video & Link	Title	Description	Inspired in the article
10 https://youtu.be /neobG3tqmV4	P4Work Pain at work? Be active	In this video you will learn about different practical strategies to manage and prevent musculoskeletal pain at the workplace. This video is intended for a public audience who	The episode is inspired by the idea awarded at the first Prevent4Work Symposium held in Milan on November 15th, 2019.
11 https://youtu.be /-ncVBf5rSrU	P4Work Benefits from ergonomic interventions for musculoskeletal pain management at work	want to learn more about the topic. In this video you will learn about the current evidence of several ergonomic interventions intended to prevent and manage musculoskeletal pain in the upper limb and neck among office workers. This video is intended for a public audience who	Hoe VC, Urquhart DM, Kelsall HL, Zamri EN, Sim MR. Ergonomic interventions for preventing work- related musculoskeletal disorders of the upper limb and neck among office workers. Cochrane Database Syst Rev. 2018 Oct 23:10(10):CD008570
12 https://youtu.be /8yKWk2oE85	P4Work Low Back Pain Course for workers	the topic. Introduction to the course "Low Back Pain", addressed to workers for all activity sectors and occupations	23,10(10).0000370.
13 https://youtu.be /Vp5IwXiVu8c	P4Work Current evidence for the treatment and management of Low Back Pain	In this video you will learn more about the management and treatment options of Low Back Pain according to current evidence-based guidelines. This video is intended for a public audience who want to learn more about the topic.	Foster NE, Anema JR, Cherkin D, Chou R, Cohen SP, Gross DP, Ferreira PH, Fritz JM, Koes BW, Peul W, Turner JA, Maher CG; Lancet Low Back Pain Series Working Group. Prevention and treatment of low back pain: evidence, challenges, and promising directions. Lancet. 2018 Jun 9;391(10137):2368- 2383.

# Video & Link	Title	Description	Inspired in the article
14 https://youtu.be /iaP4YnUXRj A	P4Work Neck Pain Course for workers	Introduction to the "Neck Pain course", addressed to workers for all activity sectors and occupations.	
15 https://youtu.be /oDoySdozQK I	P4Work How to help reduce the burden of Low Back Pain	In this video you will learn about what information health providers can offer to help those patients suffering from acute or chronic low back pain. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Lim YZ, Chou L, Au RT, Seneviwickrama KMD, Cicuttini FM, Briggs AM, Sullivan K, Urquhart DM, Wluka AE. People with low back pain want clear, consistent and personalised information on prognosis, treatment options and self- management strategies: a systematic review. J Physiother. 2019 Jul:65(3):124-135.
16 https://youtu.be /WSoWBDsQI cY	P4Work How does Low Back Pain behave?	In this video you will learn about the most common symptoms trajectories for low back pain. You will know about practical strategies for advising individual patients on how to behave in the presence of low back pain. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, Hoy D, Karppinen J, Pransky G, Sieper J, Smeets RJ, Underwood M; Lancet Low Back Pain Series Working Group. What low back pain is and why we need to pay attention. Lancet. 2018 Jun 9;391(10137):2356- 2367.
17 <u>https://youtu.be</u> /tBMjdNIZwI0	P4Work Predicting factors for Low Back Pain	In this video you will learn about some of the factors related to positive or negative outcomes of low back pain. This video is intended for a public audience who want to learn more about the topic.	Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, Hoy D, Karppinen J, Pransky G, Sieper J, Smeets RJ, Underwood M; Lancet Low Back Pain Series Working Group. What low back pain is and why we need to pay

# Video & Link	Title	Description	Inspired in the article
			attention. Lancet. 2018 Jun 9;391(10137):2356- 2367.
18 https://youtu.be /kXBnxSlilDA	P4Work Epidemiology of Low Back Pain	In this video you will learn about the social and economic impact of low back pain and what the evolution perspectives for the future are. This video is intended for a public audience who want to learn more about the topic.	Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, Hoy D, Karppinen J, Pransky G, Sieper J, Smeets RJ, Underwood M; Lancet Low Back Pain Series Working Group. What low back pain is and why we need to pay attention. Lancet. 2018 Jun 9:391(10137):2356
	0	4	2367.
19 https://youtu.be /eWdm4H5yT YU	P4Work Neuroscience Education for Chronic Low Back Pain	In this video you will learn about what Pain Neuroscience Education (PNE) is and why it is used. This video is intended for a public audience who want to learn more about the topic.	Tegner H, Frederiksen P, Esbensen BA, Juhl C. Neurophysiological Pain Education for Patients with Chronic Low Back Pain: A Systematic Review and Meta-Analysis. Clin J Pain. 2018 Aug: 34(8):778-786
20 https://youtu.be /k0J08OUw8p c	P4Work What is neck pain?	In this video you will learn about what neck pain is, its classification, its prognosis, and some guidelines for neck pain management. This video is intended for a public audience who want to learn more about the topic.	Parikh P, Santaguida P, Macdermid J, Gross A, Eshtiaghi A. Comparison of CPG's for the diagnosis, prognosis and management of non- specific neck pain: a systematic review. BMC Musculoskelet Disord. 2019 Feb 14;20(1):81.

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# Video & Link	Title	Description	Inspired in the article
21 https://youtu.be /sS- Cxg_RO7A	P4Work What is the current evidence for the management and treatment of Neck Pain?	In this video you will learn more about the management and treatment options of non- specific neck pain according to current evidence-based guidelines.	Sterling M, de Zoete RMJ, Coppieters I, Farrell SF. Best Evidence Rehabilitation for Chronic Pain Part 4: Neck Pain. J Clin Med. 2019 Aug 15;8(8):1219.
	KON PRE	This video is intended for a public audience who want to learn more about the topic.	Ainpradub K, Sitthipornvorakul E, Janwantanakul P, van der Beek AJ. Effect of education on non- specific neck and low back pain: A meta- analysis of randomized controlled trials. Man Ther. 2016 Apr;22:31- 41.
		review on	Miyamoto GC, Lin CC, Cabral CMN, van Dongen JM, van Tulder MW. Cost- effectiveness of exercise therapy in the treatment of non- specific neck pain and low back pain: a systematic review with meta-analysis. Br J Sports Med. 2019 Feb;53(3):172-181.
22 https://youtu.be /jdUYCN6Zb6 4	P4Work Low Back Pain classification	In this video you will learn about the specific pathologies associated with low back pain and clinical presentations, indicating the risk of severe pathology. This video is intended for a public audience who want to learn more about the topic.	Henschke N, Maher CG, Ostelo RW, de Vet HC, Macaskill P, Irwig L. Red flags to screen for malignancy in patients with low- back pain. Cochrane Database Syst Rev. 2013 Feb 28;(2):CD008686. Premkumar A, Godfrey W, Gottschalk MB, Boden SD. Red

	Flags for Low Back Pain Are Not Always Really Red: A Prospective Evaluation of the Clinical Utility of Commonly Used Screening Questions for Low Back Pain. J Bone Joint Surg Are
In this video you will learn about how to optimize lifestyle in people with chronic pain. This video is intended for a public audience who want to learn more about the topic. In this video you will learn why work is a resource that should be maintained, even if working is not pain-free. This video is intended for a public audience who want to learn more about the topic.	2018 Mar 7;100(5):368-374. Parikh P, Santaguida P, Macdermid J, Gross A, Eshtiaghi A. Comparison of CPG's for the diagnosis, prognosis and management of non- specific neck pain: a systematic review. BMC Musculoskelet Disord. 2019 Feb 14;20(1):81. Cullen KL, Irvin E, Collie A, Clay F, Gensby U, Jennings PA, Hogg-Johnson S, Kristman V, Laberge M, McKenzie D, Newnam S, Palagyi A, Ruseckaite R, Sheppard DM, Shourie S, Steenstra I, Van Eerd D, Amick BC 3rd. Effectiveness of Workplace Interventions in Return-to-Work for Musculoskeletal, Pain- Related and Mental Health Conditions: An Update of the Evidence and Messages for Practitioners. J Occup Rehabil. 2018 Mar;28(1):1-15.
	In this video you will learn about how to optimize lifestyle in people with chronic pain. This video is intended for a public audience who want to learn more about the topic. In this video you will learn why work is a resource that should be maintained, even if working is not pain-free. This video is intended for a public audience who want to learn more about the topic.

# Video & Link	Title	Description	Inspired in the article
			Lindholm, L. et al. Does unemployment contribute to poorer health-related quality of life among Swedish adults?. BMC Public Health 19, 457 (2019).
25 https://youtu.be /QWwM9a100 Oc	P4Work Epidemiology of Neck Pain	In this video you will learn about the social and economic impact of neck pain and what are the statistics of neck pain on a global scale. This video is intended for a public audience who want to learn more about the topic.	Safiri S, Kolahi AA, Hoy D, Buchbinder R, Mansournia MA, Bettampadi D, Ashrafi- Asgarabad A, Almasi- Hashiani A, Smith E, Sepidarkish M, Cross M, Qorbani M, Moradi-Lakeh M, Woolf AD, March L, Collins G, Ferreira ML. Global, regional, and national burden of neck pain in the general population, 1990-2017: systematic analysis of the Global Burden of Disease Study 2017. BMJ. 2020 Mar 26;368:m791. Hallman DM, Holtermann A, Dencker-Larsen S, et alAre trajectories of neck–shoulder pain associated with sick leave and work ability in workers? A 1-year prospective studyBMJ Open 2019;9:e022006.
# Video & Link	Title	Description	Inspired in the article
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26 https://youtu.be /frMTiNSf7P4	P4Work How to reduce Work- related Neck Pain	In this video you will learn about what physical exercises can be performed using a rubber band in order to reduce neck pain. This video is intended for a public audience who want to learn more about	Parikh P, Santaguida P, Macdermid J, Gross A, Eshtiaghi A. Comparison of CPG's for the diagnosis, prognosis and management of non- specific neck pain: a systematic review. BMC Musculoskelet
27 https://youtu.be /yIqUyw526M o	P4Work Is working good for you? (1): Health, work, and wellbeing	In this video you will learn about how work, health, and wellbeing may influence each other. This video is intended for a public audience who want to learn more about the topic.	Disord. 2019 Feb14;20(1):81.Waddell G, BurtonAK. Is work good foryour health and well-being? The StationeryOffice, London, UK.(2006) ISBN9780117036949
28 <u>https://youtu.be</u> <u>/tIy6mqMHZh</u> g	P4Work Is working good for you? (2): Unemployment and health	In this video you will learn about how unemployment can actually influence our mental and physical health. This video is intended for a public audience who want to learn more about the topic.	Waddell G, Burton AK. Is work good for your health and well- being? The Stationery Office, London, UK. (2006) ISBN 9780117036949
29 https://youtu.be /qKNZT3RuCa 0	P4Work Is working good for you? (3): Employment and health	In this video you will learn about the benefits that meaningful employment has on our health. This video is intended for a public audience who want to learn more about the topic.	Waddell G, Burton AK. Is work good for your health and well- being? The Stationery Office, London, UK. (2006) ISBN 9780117036949
30 https://youtu.be /ywtIBLsoQHg	P4Work Is working good for you? (4): Re- employment and health	In this video you will learn about the therapeutic effect of getting back into the workforce after a period of unemployment.	Waddell G, Burton AK. Is work good for your health and well- being? The Stationery Office, London, UK.

# Video & Link	Title	Description	Inspired in the article
		This video is intended for a public audience who want to learn more about the topic.	(2006) ISBN 9780117036949
31 https://youtu.be /wLuhGLFtelw	P4Work Is working good for you? (5): Therapeutic effect for Musculoskeletal Pain	In this video you will learn about the benefits of employment and re- employment for people with musculoskeletal pain and why work should be considered therapeutic. This video is intended for a public audience who want to learn more about	Waddell G, Burton AK. Is work good for your health and well- being? The Stationery Office, London, UK. (2006) ISBN 9780117036949

want to learn more about the topic.

BMJ Open

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EUROPEAN KNOWLEDGE ALLIANCE FOR INNOVATIVE MEASURES IN PREVENTION OF WORK-RELATED MUSCULOSKELETAL PAIN DISORDERS (PREVENT4WORK PROJECT): PROTOCOL FOR AN INTERNATIONAL MIXED METHODS LONGITUDINAL STUDY

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Original paper for BMJ Open

EUROPEAN KNOWLEDGE ALLIANCE FOR INNOVATIVE MEASURES IN PREVENTION OF WORK-RELATED MUSCULOSKELETAL PAIN **DISORDERS (PREVENT4WORK PROJECT): PROTOCOL FOR AN** INTERNATIONAL MIXED METHODS LONGITUDINAL STUDY

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ABSTRACT

Introduction

Work-related musculoskeletal (MSK) pain is a highly prevalent condition and one of the main contributors to disability and loss of work capacity. Current approaches to the management and prevention of work-related MSK pain do not consistently integrate current evidence-based knowledge and seem to be outdated. The Prevent4Work (P4W) project aims to collect and spread evidence-based information to improve the management and prevention of work-related MSK pain. P4W will longitudinally investigate i) risk factors associated with the prevalence of work-related MSK pain, ii) predictive factors for new events of work-related MSK pain in the short term, and iii) the modification of pain beliefs after participating in evidence-based e-learning courses.

Methods and analysis

This project employs a mixed-methods design with international cohorts of workers from Spain, Italy, and Denmark. All participants will be assessed using self-reported variables at baseline (i.e., cross-sectional design) with follow-up after 3 and 6-months (i.e., prospective-predictive design). Throughout the first phase (0-3 months), all participants will be offered to self-enroll in e-learning courses on work-related MSK pain. Changes in pain beliefs (if any) will be assessed. The dataset will include sociodemographic characteristics, physical and psychological job demands, lifestyle-related factors, MSK pain history, and pain beliefs. At baseline, all participants will additionally complete the P4W questionnaire developed to detect populations at high risk of suffering work-related MSK pain.

Descriptive statistics, binary logistic regression, and analysis of variance will be used to identify the significant factors that influence the history of work-related MSK pain, evaluate the short-term prediction capacity of the P4W questionnaire, and

investigate whether workers' participation in e-learning courses will modify their pain beliefs.

Ethics and dissemination

The study received ethical approval from the Ethical Committee of San Jorge University (USJ011-19/20). The results will be made available via peer-reviewed publications, international conferences and Prevent4Work official channels.

Strengths and limitations of this study

- Large multicenter study examining risk factors associated with work-related MSK pain in three different European countries.
- Comprehensive multidimensional assessment of workers is conducted.
- A prospective design protocol which allows to investigate the temporal dynamics of work-related MSK pain.
- Only short-term follow-up is conducted.
- Only self-reported variables but no subject-independent measures are obtained.

Key Words:

Occupational & Industrial medicine, Musculoskeletal Disorders, Pain Management.

INTRODUCTION

Work-related musculoskeletal (MSK) pain refers to pain related to or leading to workrelated disability.¹ The level of disability can range from low to high and be episodic or persistent, thus reducing workers' quality of life and work capacity.² Self-reported pain in the neck and low back is the main complaint of workers reporting interfering pain.³ According to the Sixth European Working Conditions Survey, 40% of workers report one event of pain per year, while 20% report having a chronic pain condition.⁴

Work-related MSK pain is a complex condition, consisting of multiple interacting factors such as i) physical factors (e.g., manual handling, working in awkward postures, repetitive work, and working at high speed), ii) individual factors (e.g., stress exposure, health believes, beliefs about pain, sleep quality, social support), iii) contextual factors (e.g., workplace design and organization) and, iv) sociodemographic factors (e.g., level of education, age).⁵

The incidence and prevalence rates of work-related MSK pain are increasing world-wide, which may indicate a sub-optimal effect of contemporary approaches for its management.⁶ Insufficient implementation of evidence-based practice might be the primary contributor,⁷ although outdated education of health care professionals and low-value treatments are also barriers for optimal management of work-related MSK pain.⁸⁹

Previous, large-scale initiatives have demonstrated that educational interventions can modify pain beliefs among workers.¹⁰ Therefore, given that outdated beliefs and expectations about health are associated with a higher risk of work-related MSK pain¹¹ and potentially with chronicity and disability,¹² educational interventions could be an ideal starting point. However, the impact of changes in pain beliefs on reducing new events and/or chronicity of work-related MSK pain has not yet been investigated.

Prevent4Work project:

The European Knowledge Alliance "Prevent4Work" (P4W) project aims to provide highquality education for professionals and laypeople focusing on work-related MSK pain. This initiative is intended to improve work-related MSK pain management strategies by developing and implementing new assessment and interactive digital platforms. A part of this initiative is the risk assessment questionnaire (P4W questionnaire) has recently been developed to detect populations at high risk of suffering work-related MSK pain.¹³ Moreover, innovative educational programs will be introduced, and adaptive mobile interactive digital platforms, capable of delivering evidence-based information and collect data will be continuously developed (Supplemental Table 1).

The research-specific aims of the P4W project are i) to identify risk factors associated with the prevalence and/or the incidence of work-related MSK pain, ii) to evaluate the predictive capacity of the P4W questionnaire for new events of work-related MSK pain in the short term (i.e., three and six months), iii) to evaluate whether pain beliefs are modified in the short term after participating in e-learning evidence-based training activities about work-related MSK pain.

It has been suggested that the pandemic situation related to COVID-19 has had a significant negative effect on the physical and mental wellbeing of people with chronic pain.¹⁴ Additionally, there is insufficient data on how/if the COVID-19 pandemic causes new events or flare-ups of pain across the successive waves of contagion.¹⁵ Therefore, the project will explore potential relationships with the development of new events of self-reported work-related MSK pain.

METHODS

The present study protocol complies with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations.¹⁶

Study design

This study protocol will follow a longitudinal mixed-methods design with international cohorts. All participants will be assessed by using self-reported variables at baseline (i.e., cross-sectional study design) with follow-up at 3 and 6-months (i.e., prospective-predictive study design). Throughout the first phase (0-3 months), all participants will be offered to self-enroll in a free-learning course about work-related MSK pain. The analysis of data will be performed following a pragmatic study design (see figure 1).

FIGURE 1 HERE

Population

The cohort will be composed of people in employment between 18 and 65 years of age, from Denmark, Italy, and Spain, who are fluent in either English, Danish, Italian, or Spanish, who have an easy access to a tablet/smartphone and internet. No specific exclusion criteria will be considered to be enrolled in the study. In the event of an enrolled participant changing the initial job position or taking any sort of long-term leave during the study period, he/she will be excluded from the follow-up analysis.

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Contact and recruitment

Companies, institutions, and workers associations from Denmark, Italy, and Spain are invited to participate in P4W actions via the P4W network. Each organization will provide their workers information in the local language together with two animated videos (also in the local language) explaining the aims and actions of the P4W project. The participants recruited through here will provide data that will enable an evaluation of risk factors associated with work-related MSK pain. Likewise, their participation in the P4W e-learning courses about work-related MSK pain will allow for an evaluation of the content from a user perspective. Participating organizations will be assigned a national liaison for first-line support.

Data collection and security measures

Data collection will be conducted between April and December 2021. When registering in the application for mobile devices (app), participants will have to accept the informed consent before they get a personal account. Two reminder messages will appear within the main panel of the app, with the first one notifying which institution is leading the project in their country of residence while the second will be a reminder of that the survey and P4W questionnaire is ready to be completed.

All personal and survey data will be stored with record-level encryption at the database level, meaning that it is incomprehensible without first being decrypted. Moreover, the survey data will be pseudo-anonymized, so it is impossible to relate the physical person and with their data directly. For processing and exporting purposes, all data will be conveniently anonymized in a way that each data record is generated with a unique identifier that is not possible to relate with the physical person and its personal information.

All the measures will be conducted to comply with EU's General Data Protection Regulation ¹⁷ and implemented following recommended guidelines.¹⁸

P4W courses

All participants can choose to participate in one or more e-learning courses. The P4W study group published a scoping review on the role of education in preventing and treating work-related MSK pain, finding that there is a basis for using education to complement other treatments.¹ Here, participants can access animated videos with essential messages from systematic reviews on work-related MSK pain which have been produced specifically in relation to the project (Supplemental Table 2). The videos were developed in English and Spanish languages, with Italian or Danish subtitles and are publicly available at https://p4work.com/results/ (retrieved on 31st March 2021). For further analysis, all participants that have been invited to take the courses will be classified based to their interaction with the animated videos as: i) No participation at all, ii) Visualization of videos in isolation / Starting, but not finishing an e-learning course, iii) Completion of one or more entire learning courses.

Outcome measures

Table 1 summarizes outcome domains over the length of the study. Specific outcomes measures are presented in detail afterward.

Table 1. Summary of outcome domains assessed over the length of the study, including risk factors potentially associated with prevalence and/or incidence of work-related MSK pain.

Period	Domains	
	• P4W survey	
	 Individual factors 	
Baseline	 Job demands 	
	• Lifestyle	
	• MSK pain history	

	o COVID-19
	• Pain Beliefs
	• Work-related MSK pain training
	experience and interests
	• P4W questionnaire
	• P4W follow-up survey
	• Verification of same job position
	• Verification of e-learning course
3- and 6-month follow-up	participation
5 und 6 monul follow up	o Lifestyle
	 MSK pain history
	o COVID-19
	• Pain Beliefs

<u>Baseline</u>

At baseline, all participants will complete a survey composed of 5 sections:

<u>Section 1</u>: This section will collect sociodemographic and personal information such as age, sex, weight, height, education level, job position and seniority.

<u>Section 2</u>: This section will collect information about job demands at different levels such as physical demand, psychological demand, and decision capacity. Each domain is composed of different questions assessed on a 5-item Likert scale. The average scores of the different questions in each domain are classified as being in "high demand", "medium demand" or "low demand".²⁰ Following the same structure, four additional categories will be assessed in the P4W survey: "sustained postures", "repetitive movement", "overstrain", and "overtime".

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<u>Section 3</u>: This section will collect information about lifestyle (physical activity out of work, sleep quality and quantity), medical history of MSK pain (including onset e.g., whiplash injury due to a car accident) and COVID-19 impact.

- **Physical activity** in leisure time will be evaluated by using the Global Physical Activity Questionnaire²¹ proposed by the World Health Organization. Participants will be asked to indicate the number of days (if any) in a typical week and the average time in a day (in hours and minutes) they spend doing such type of moderate or vigorous intensity activities.
- Sleep quality will be evaluated by using the Medical Outcomes Study Sleep Scale.²² Specifically, the sleep adequacy domain, composed of only 2 questions, will be assessed. This domain is rated on a 6-item Likert scale, and the average of the two questions is transformed to a percentage. Sleep quantity will be assessed by asking for the average number of hours slept per night during the last 4 weeks.
- Prevalence and history of self-reported work-related MSK pain will be evaluated using the extended version of the Nordic Musculoskeletal Questionnaire.²³ The original 9 body regions in the original scale will be reduced to 4 (neck pain, low back pain, upper limb pain and lower limb pain). As part of the extended version, medication consumption, use of health services (physiotherapist, doctor, etc.) and difficulties to carry out work tasks, will be registered to evaluate the impact of MSK pain in workers.
- **COVID-19 impact** will be explored as a potential contributor to developing or aggravating MSK pain¹⁵ by using supplementary, ad hoc questions.

<u>Section 4</u>: Information about beliefs related to the cause and treatment of pain are collected using the Pain Beliefs Questionnaire.²⁴ The Pain Beliefs Questionnaire is a

12-item questionnaire with a 6-point Likert scale that taps into the two dimensions of pain beliefs (organic and psychological beliefs).

<u>Section 5</u>: This section will collect information about the participants' training experience and interests in the field of work-related MSK pain. The different topics are based on the current management of work-related MSK pain and the latest evidence regarding factors and interventions that can contribute to increase or decrease the risk of suffering work-related MSK pain.⁵

<u>Prevent4Work Questionnaire</u>: All workers will complete the P4W questionnaire. This self-perceived risk assessment questionnaire was developed to detect populations at high risk of work-related MSK pain.¹³ The instrument uses a biopsychosocial approach based on 20 items with a 5-point Likert scale which investigates four different domains: Physical Stress, Mental Stress, Job Satisfaction and Kinesiophobia.

Follow-up at 3 and 6 months

 At follow-up (3 and 6-months), all participants will receive a short version of the survey conducted at baseline. This short version of the survey will be composed of i) a specific question to ensure the participant is performing the same job and type of work as baseline level, ii) a specific self-reported question related to the participation in e-learning courses, iii) a short version of the Nordic Musculoskeletal Questionnaire regarding the experience of new events of self-reported MSK pain in the last 3-6 months, and iv) the Pain Beliefs Questionnaire.

Data from the 3-month follow-up will be used to evaluate any potential change in pain beliefs, whilst 6-month follow-up will be used to test the short-term prediction

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capacity of the P4W questionnaire for new events of MSK pain (at the neck, low back, upper limb, or lower limb) within the cohort of workers.

Sample size

The present large-scale project needs to reach a sample of 1.500 workers to meet the European Commission requirements and analyze the current risk factors for MSK pain. This sample size is estimated to be valid to test the short-term prediction capacity of P4W questionnaire for a new event of self-reported MSK pain based on performing a binary logistic regression.²⁵ Under these circumstances, at least 331 workers should be followed-up at 6 months in order to evaluate the predictive capacity of 10 candidate variables with an incidence expectation of $15\pm5\%$ for a new episode of self-reported MSK pain.^{26 27} Additionally, the sample size (n>158) will allow for detecting small to medium differences within workers in the Pain Beliefs Questionnaire (Cohen's effect size d= $0.26)^{28}$ with an alfa error of 0.05 and a power of 90%.

Statistical analysis

In relation to the first aim, linked to the cross-sectional study, multiclass or binary logistic regression will be applied to identify the major factors that influence the presence and/or recent history of work-related MSK pain. In relation to the second aim, linked to the cohort study, binary logistic regression will be used to evaluate the short-term prediction capacity of the P4W questionnaire with regards to the appearance of a new MSK pain event in the past 6 months according to the Nordic Musculoskeletal Questionnaire. In relation to the third aim, linked to the pragmatic study, repeated measures analysis of variance will be used to determine if workers' participation in e-learning courses modifies their pain beliefs. The analysis will be conducted under the intention-to-treat and perprotocol principles, and the effect sizes will be reported for a better interpretation and

controlling the risk of type-1 error. The significance level will be established for all the analyses at P<0.05.

Ethics and confidentiality

The study protocol has been approved by the ethical committee at San Jorge University (USJ011-19/20). Each participant will be automatically assigned a study code when registering on the app. This code will be the only downloadable information together with health data by study researchers. All personal data needed for registration will be saved in an independent database, which will only be accessible by the principal investigator and study coordinators in each country. Any deviation from the current protocol will be explained and justified if necessary.

Dissemination

The results, regardless of the outcome, will be made available via peer-reviewed publications in open-source journals, relevant international conferences within the field of pain and occupational health, and via P4W official channels, such as the P4W website, social media channels, and final project symposium. Results will likewise be disseminated by producing new high-quality videos on the P4W YouTube channel.

REFERENCES

 Palsson TS, Boudreau S, Høgh M, et al. Education as a strategy for managing occupational-related musculoskeletal pain: a scoping review. *BMJ Open* 2020;10(2):e032668.

- Chang YF, Yeh CM, Huang SL, et al. Work Ability and Quality of Life in Patients with Work-Related Musculoskeletal Disorders. *Int J Environ Res Public Health* 2020;17(9)
 - 3. de Kok J, Vroonhof P, Snijders J, et al. Work-related musculoskeletal disorders: prevalence, costs and demographics in the EU. Luxembourg: European Agency for Safety and Health at Work 2019. Available: https://osha.europa.eu/sites/default/files/publications/documents/Workrelated MSDs prevalence costs and demographics in the EU report.pdf
 - 4. Parent-Thirion A, Biletta I, Cabrita J, et al. Sixth European Working Conditions Survey

 Overview report (2017 update). Luxembourg: European Foundation for the
 Improvement of Living and Working Conditions 2017. Available:
 https://www.eurofound.europa.eu/sites/default/files/ef_publication/field_ef_doc
 ument/ef1634en.pdf
 - 5. Isusi I. Work-related musculoskeletal disorders Facts and figures. Luxembourg: European Agency for Safety and Health at Work 2020. Available: https://osha.europa.eu/sites/default/files/publications/documents/Work_related_ musculoskeletal_disorders_%20Facts_and_figures.pdf
- 6. Crawford JO, Davis A. Work-related musculoskeletal disorders: why are they still so prevalent? Evidence from a literature review. Luxembourg: European Agency for Safety and Health at Work 2020. Available: https://osha.europa.eu/sites/default/files/publications/documents/Work_related_ musculoskeletal disorders why so prevalent report.pdf
- Buchbinder R, Underwood M, Hartvigsen J, et al. The Lancet Series call to action to reduce low value care for low back pain: an update. *Pain* 2020;161 Suppl 1(1):S57-S64.

- Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet* 2018;**391**(10137):2368-83.
- 9. Slade SC, Kent P, Patel S, et al. Barriers to Primary Care Clinician Adherence to Clinical Guidelines for the Management of Low Back Pain: A Systematic Review and Metasynthesis of Qualitative Studies. *Clin J Pain* 2016;**32**(9):800-16.
- Andersen LL, Geisle N, Knudsen B. Can beliefs about musculoskeletal pain and work be changed at the national level? Prospective evaluation of the Danish national Job & Body campaign. *Scand J Work Environ Health* 2018;44(1):25-36.
- Vargas-Prada S, Coggon D. Psychological and psychosocial determinants of musculoskeletal pain and associated disability. *Best Pract Res Clin Rheumatol* 2015;29(3):374-90.
- 12. Coggon D, Ntani G, Palmer KT, et al. Disabling musculoskeletal pain in working populations: is it the job, the person, or the culture? *Pain* 2013;**154**(6):856-63.
- Langella F, Christensen SWM, Palsson TS, et al. Development of the Prevent for Work questionnaire (P4Wq) for assessment of musculoskeletal risk in the workplace: part 1-literature review and domains selection. *BMJ Open* 2021;11(4):e043800.
- Carrillo-de-la-Peña MT, González-Villar A, Triñanes Y. Effects of the COVID-19 pandemic on chronic pain in Spain: a scoping review. *Pain Rep* 2021;6(1):e899.
- 15. Cipollaro L, Giordano L, Padulo J, et al. Musculoskeletal symptoms in SARS-CoV-2 (COVID-19) patients. *J Orthop Surg Res* 2020;15(1):178.
- von Elm E, Altman DG, Egger M, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *BMJ* 2007;**335**(7624):806-8.

- 17. 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 repealing Directive 95/46/EC (General Data Protection Regulation). *Official Journal of the European Union* 2016;119(1)
 - 18. Agencia Española de Protección de Datos A. Orientaciones y garantías en los procedimientos de anonimización de datos personales. 2016. Available: https://www.aepd.es/sites/default/files/2019-09/guia-orientacionesprocedimientos-anonimizacion.pdf
 - 19. Agencia Española de Protección de Datos A. Guía del Reglamento General de Protección de Datos para responsables de tratamiento. 2016. Available: https://www.aepd.es/sites/default/files/2019-09/guia-rgpd-para-responsables-detratamiento.pdf
 - 20. Cantley LF, Tessier-Sherman B, Slade MD, et al. Expert ratings of job demand and job control as predictors of injury and musculoskeletal disorder risk in a manufacturing cohort. *Occup Environ Med* 2016;**73**(4):229-36.
 - 21. Wanner M, Hartmann C, Pestoni G, et al. Validation of the Global Physical Activity Questionnaire for self-administration in a European context. *BMJ Open Sport Exerc Med* 2017;3(1):e000206.
 - 22. Hays RD, Martin SA, Sesti AM, et al. Psychometric properties of the Medical Outcomes Study Sleep measure. *Sleep medicine* 2005;**6**(1):41-4.
 - 23. Dawson AP, Steele EJ, Hodges PW, et al. Development and test-retest reliability of an extended version of the Nordic Musculoskeletal Questionnaire (NMQ-E): a screening instrument for musculoskeletal pain. *The journal of pain : official journal of the American Pain Society* 2009;**10**(5):517-26.

- 24. Edwards LC, Pearce SA, Turner-Stokes L, et al. The Pain Beliefs Questionnaire: an investigation of beliefs in the causes and consequences of pain. *Pain* 1992;**51**(3):267-72.
- Riley RD, Ensor J, Snell KIE, et al. Calculating the sample size required for developing a clinical prediction model. *BMJ* 2020;368:m441.
- 26. Ostergren PO, Hanson BS, Balogh I, et al. Incidence of shoulder and neck pain in a working population: effect modification between mechanical and psychosocial exposures at work? Results from a one year follow up of the Malmö shoulder and neck study cohort. *J Epidemiol Community Health* 2005;**59**(9):721-8.
- 27. Vargas-Prada S, Serra C, Martínez JM, et al. Psychological and culturally-influenced risk factors for the incidence and persistence of low back pain and associated disability in Spanish workers: findings from the CUPID study. *Occup Environ Med* 2013;**70**(1):57-62.
- 28. Baird AJ, Haslam RA. Exploring differences in pain beliefs within and between a large nonclinical (workplace) population and a clinical (chronic low back pain) population using the pain beliefs questionnaire. *Phys Ther* 2013;93(12):1615-24.

FIGURE LEGEND

Figure 1. Study timeline design.

TABLE LEGEND

Table 1. Summary of outcome domains assessed over the length of the study, including risk factors potentially associated with prevalence and/or incidence of work-related MSK pain.

DECLARATIONS

Authors' contributions

All authors contributed significantly to the design of this study protocol and conformed to the requirements of the International Committee of Medical Journal Editors (ICMJE). PBL, VDG, TSP, SWMC, PBS, FL, PB, PH and MH contributed to the conception and planning of the study protocol. PBL, VDG, TSP, PBS, AR, PB and MH contributed to the acquisition of the data for the work. PBL, VDG, TSP, SWMC, PBS, PSJ, FL, PB, AB, JBA, CJS, SC, DJC, PH and MH contributed to the development of educational content and evaluation tools. All authors contributed to writing the article and have read and approved the final manuscript.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

<text><text><section-header><text>



Supplemental table 1. List of P4W links resources: innovative educational programs and adaptive mobile interactive digital platforms for delivering evidence-based information and collecting data.

Resource	Link
P4W web page	https://p4work.com/
P4W app for iOS	https://apps.apple.com/es/app/p4work/id1 509417286
P4W app for Android	https://play.google.com/store/apps/details ?id=com.geoslab.p4w&hl=es
P4W e-learning platform	https://aulaonline.p4work.com/
P4W Youtube channel	https://www.youtube.com/channel/Preve nt4Work
P4W Facebook account	https://www.facebook.com/Prevent4Wor k-558730587928229/
P4W Linkedin profile	https://www.linkedin.com/company/prev ent4work/
P4W video presentation	https://youtu.be/PNcVgohx1jw
P4W app videotutorial	https://youtu.be/M6mDbN6itIw
P4W e-learning platform videotutorial	https://youtu.be/S0ORsO0ECZk

Supplemental table 2. List of P4W animated educational videos with essential messages

and evidence-based information related to musculoskeletal pain and work.

# Video & Link	Title	Description	Inspired in the article
1 https://youtu.be /7cao2oIyomg	P4Work Best Practices for Musculoskeletal Pain management (1): Patient- Centred Care	This is the first of three videos where you will learn about the best recommendations for addressing musculoskeletal pain in your clinical practice. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan;54(2):79-86.
2 https://youtu.be /3qBWsV_v2n M	P4Work Best Practices for Musculoskeletal Pain management (2): Clinical Screening	This is the second of three videos where you will learn about the best recommendations for addressing musculoskeletal pain in your clinical practice. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan:54(2):79-86.
3 https://youtu.be /wxlOG1yRVS g	P4Work Best Practices for Musculoskeletal Pain management (3): Interventions and Recommendations	This is the third of three videos where you will learn about the best recommendations for addressing musculoskeletal pain in your clinical practice. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan;54(2):79-86.

# Video & Link	Title	Description	Inspired in the article
4 <u>https://youtu.be</u> <u>/k1CAyUDr1x</u> <u>I</u>	P4Work Recommendations for people suffering from Musculoskeletal Pain	In this video you will learn about the best and updated recommendations for people having musculoskeletal pain. This video is intended for a public audience who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan:54(2):79-86
5 https://youtu.be /Bad9Wjb0hU U	P4Work Best scientific evidence on self- management programs for chronic low back pain	This video you will learn about the importance of the self-management program for chronic low back pain. It wants to teach people how to manage their pain and better-known related care decisions. This video is intended for a public audience who want to learn more about the topic.	Lin I, Wiles L, Waller R, Goucke R, Nagree Y, Gibberd M, Straker L, Maher CG, O'Sullivan PPB. What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. Br J Sports Med. 2020 Jan;54(2):79-86 Du S, Hu L, Dong J, Xu G, Chen X, Jin S, Zhang H, Yin H. Self- management program for chronic low back pain: A systematic review and meta- analysis. Patient Educ Couns. 2017 Jan:100(1):37.49

# Video & Link	Title	Description	Inspired in the article
6	P4Work What	In this video you will	Hartvigsen J, Hancock
	everyone should	learn about the concept	MJ, Kongsted A, Louw
https://youtu.be	know about low	of "Low Back Pain" and	Q, Ferreira ML,
/9De7xeDATG	back pain	related issues such as	Genevay S, Hoy D,
U	1	prevalence, prognosis,	Karppinen J, Pransky
—		and evidence-based recommendations for its	G, Sieper J, Smeets RJ, Underwood M; Lancet
		management.	Low Back Pain Series Working Group. What
		This video is intended for	low back pain is and
		a public audience who	why we need to pay
		want to learn more about	attention. Lancet. 2018
		the topic.	Jun
			9;391(10137):2356- 2367.
	0		Foster NE, Anema JR,
			Cherkin D, Chou R,
			Cohen SP, Gross DP,
			Ferreira PH, Fritz JM,
			Koes BW, Peul W,
		~	Turner JA, Maher CG;
			Lancet Low Back Pain
			Series Working Group.
		6.	Prevention and
			treatment of low back
			pain: evidence,
			challenges, and
		7	promising directions.
			Lancet. 2018 Jun
			9;391(10137):2368-
			2383.
7	P4Work	In this video you will	Hayden JA, Wilson
	Recovery	learn more about how	MN, Riley RD, Iles R,
https://youtu.be	expectations and	positive or negative	Pincus T, Ogilvie R.
/aGEKmT81S-	prognosis in Low	expectations might	Individual recovery
A	Back Pain	influence return to work	expectations and
		after a low back pain	prognosis of outcomes
		episode.	in non-specific low
			back pain: prognostic
		This video is intended for	factor review.
		a public audience who	Cochrane Database
		want to learn more about	Syst Rev. 2019 Nov
		the topic.	25;2019(11):CD01128

# Video & Link	Title	Description	Inspired in the article
8 https://youtu.be /BVJy3DxUR L0	P4Work Workplace interventions to prevent work disability in workers on sick leave	In this video you will learn about the possible workplace interventions that can be conducted to prevent work disability in workers on sick leave. This video is intended for a general audience who wants to learn more about the topic. However, it is mainly meant for health professionals and persons responsible for occupational safety and health in businesses, companies, and	van Vilsteren M, van Oostrom SH, de Vet HC, Franche RL, Boot CR, Anema JR. Workplace interventions to prevent work disability in workers on sick leave. Cochrane Database Syst Rev. 2015 Oct 5;(10):CD006955.
9 https://youtu.be /j3Sh7AbdWV M	P4Work Workplace interventions to reduce musculoskeletal pain in physically demanding jobs	institutions. In this video you will learn about workplace interventions to rehabilitate musculoskeletal disorders among employees with physically demanding work. It is about interventions and attitudes to be taken in the workplace to improve musculoskeletal pain management and to prevent injuries. This video is intended for a general audience who wants to learn more about the topic. However, it is mainly meant for health professionals and persons responsible for occupational safety and health in businesses, companies, and institutions	Sundstrup E, Seeberg KGV, Bengtsen E, Andersen LL. A Systematic Review of Workplace Interventions to Rehabilitate Musculoskeletal Disorders Among Employees with Physical Demanding Work. J Occup Rehabil. 2020 Dec;30(4):588-612.

# Video & Link	Title	Description	Inspired in the article
10 https://youtu.be /neobG3tqmV4	P4Work Pain at work? Be active	In this video you will learn about different practical strategies to manage and prevent musculoskeletal pain at the workplace. This video is intended for a public audience who	The episode is inspired by the idea awarded at the first Prevent4Work Symposium held in Milan on November 15th, 2019.
11 https://youtu.be /-ncVBf5rSrU	P4Work Benefits from ergonomic interventions for musculoskeletal pain management at work	want to learn more about the topic. In this video you will learn about the current evidence of several ergonomic interventions intended to prevent and manage musculoskeletal pain in the upper limb and neck among office workers. This video is intended for a public audience who	Hoe VC, Urquhart DM, Kelsall HL, Zamri EN, Sim MR. Ergonomic interventions for preventing work- related musculoskeletal disorders of the upper limb and neck among office workers. Cochrane Database Syst Rev. 2018 Oct 23:10(10):CD008570
12 https://youtu.be /8yKWk2oE85	P4Work Low Back Pain Course for workers	the topic. Introduction to the course "Low Back Pain", addressed to workers for all activity sectors and occupations	23,10(10).0000370.
13 https://youtu.be /Vp5IwXiVu8c	P4Work Current evidence for the treatment and management of Low Back Pain	In this video you will learn more about the management and treatment options of Low Back Pain according to current evidence-based guidelines. This video is intended for a public audience who want to learn more about the topic.	Foster NE, Anema JR, Cherkin D, Chou R, Cohen SP, Gross DP, Ferreira PH, Fritz JM, Koes BW, Peul W, Turner JA, Maher CG; Lancet Low Back Pain Series Working Group. Prevention and treatment of low back pain: evidence, challenges, and promising directions. Lancet. 2018 Jun 9;391(10137):2368- 2383.

# Video & Link	Title	Description	Inspired in the article
14 https://youtu.be /iaP4YnUXRj A	P4Work Neck Pain Course for workers	Introduction to the "Neck Pain course", addressed to workers for all activity sectors and occupations.	
15 https://youtu.be /oDoySdozQK I	P4Work How to help reduce the burden of Low Back Pain	In this video you will learn about what information health providers can offer to help those patients suffering from acute or chronic low back pain. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Lim YZ, Chou L, Au RT, Seneviwickrama KMD, Cicuttini FM, Briggs AM, Sullivan K, Urquhart DM, Wluka AE. People with low back pain want clear, consistent and personalised information on prognosis, treatment options and self- management strategies: a systematic review. J Physiother. 2019 Jul:65(3):124-135.
16 https://youtu.be /WSoWBDsQI cY	P4Work How does Low Back Pain behave?	In this video you will learn about the most common symptoms trajectories for low back pain. You will know about practical strategies for advising individual patients on how to behave in the presence of low back pain. This video is mainly intended for healthcare professionals and the general public who want to learn more about the topic.	Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, Hoy D, Karppinen J, Pransky G, Sieper J, Smeets RJ, Underwood M; Lancet Low Back Pain Series Working Group. What low back pain is and why we need to pay attention. Lancet. 2018 Jun 9;391(10137):2356- 2367.
17 https://youtu.be /tBMjdNIZwI0	P4Work Predicting factors for Low Back Pain	In this video you will learn about some of the factors related to positive or negative outcomes of low back pain. This video is intended for a public audience who want to learn more about the topic.	Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, Hoy D, Karppinen J, Pransky G, Sieper J, Smeets RJ, Underwood M; Lancet Low Back Pain Series Working Group. What low back pain is and why we need to pay

# Video & Link	Title	Description	Inspired in the article
			attention. Lancet. 2018 Jun 9;391(10137):2356- 2367.
18 https://youtu.be /kXBnxSlilDA	P4Work Epidemiology of Low Back Pain	In this video you will learn about the social and economic impact of low back pain and what the evolution perspectives for the future are. This video is intended for a public audience who want to learn more about the topic.	Hartvigsen J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, Hoy D, Karppinen J, Pransky G, Sieper J, Smeets RJ, Underwood M; Lancet Low Back Pain Series Working Group. What low back pain is and why we need to pay attention. Lancet. 2018 Jun 9:391(10137):2356
	0	4	2367.
19 https://youtu.be /eWdm4H5yT YU	P4Work Neuroscience Education for Chronic Low Back Pain	In this video you will learn about what Pain Neuroscience Education (PNE) is and why it is used. This video is intended for a public audience who want to learn more about the topic.	Tegner H, Frederiksen P, Esbensen BA, Juhl C. Neurophysiological Pain Education for Patients with Chronic Low Back Pain: A Systematic Review and Meta-Analysis. Clin J Pain. 2018 Aug: 34(8):778-786
20 https://youtu.be /k0J08OUw8p c	P4Work What is neck pain?	In this video you will learn about what neck pain is, its classification, its prognosis, and some guidelines for neck pain management. This video is intended for a public audience who want to learn more about the topic.	Parikh P, Santaguida P, Macdermid J, Gross A, Eshtiaghi A. Comparison of CPG's for the diagnosis, prognosis and management of non- specific neck pain: a systematic review. BMC Musculoskelet Disord. 2019 Feb 14;20(1):81.

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# Video & Link	Title	Description	Inspired in the article
21 https://youtu.be /sS- Cxg_RO7A	P4Work What is the current evidence for the management and treatment of Neck Pain?	In this video you will learn more about the management and treatment options of non- specific neck pain according to current evidence-based guidelines.	Sterling M, de Zoete RMJ, Coppieters I, Farrell SF. Best Evidence Rehabilitation for Chronic Pain Part 4: Neck Pain. J Clin Med. 2019 Aug 15;8(8):1219.
	KON PRE	This video is intended for a public audience who want to learn more about the topic.	Ainpradub K, Sitthipornvorakul E, Janwantanakul P, van der Beek AJ. Effect of education on non- specific neck and low back pain: A meta- analysis of randomized controlled trials. Man Ther. 2016 Apr;22:31- 41.
		review on	Miyamoto GC, Lin CC, Cabral CMN, van Dongen JM, van Tulder MW. Cost- effectiveness of exercise therapy in the treatment of non- specific neck pain and low back pain: a systematic review with meta-analysis. Br J Sports Med. 2019 Feb;53(3):172-181.
22 https://youtu.be /jdUYCN6Zb6 4	P4Work Low Back Pain classification	In this video you will learn about the specific pathologies associated with low back pain and clinical presentations, indicating the risk of severe pathology. This video is intended for a public audience who want to learn more about the topic.	Henschke N, Maher CG, Ostelo RW, de Vet HC, Macaskill P, Irwig L. Red flags to screen for malignancy in patients with low- back pain. Cochrane Database Syst Rev. 2013 Feb 28;(2):CD008686. Premkumar A, Godfrey W, Gottschalk MB, Boden SD. Red

	Flags for Low Back Pain Are Not Always Really Red: A Prospective Evaluation of the Clinical Utility of Commonly Used Screening Questions for Low Back Pain. J Bone Joint Surg Are		
In this video you will learn about how to optimize lifestyle in people with chronic pain. This video is intended for a public audience who want to learn more about the topic. In this video you will learn why work is a resource that should be maintained, even if working is not pain-free. This video is intended for a public audience who want to learn more about the topic.	2018 Mar 7;100(5):368-374. Parikh P, Santaguida P, Macdermid J, Gross A, Eshtiaghi A. Comparison of CPG's for the diagnosis, prognosis and management of non- specific neck pain: a systematic review. BMC Musculoskelet Disord. 2019 Feb 14;20(1):81. Cullen KL, Irvin E, Collie A, Clay F, Gensby U, Jennings PA, Hogg-Johnson S, Kristman V, Laberge M, McKenzie D, Newnam S, Palagyi A, Ruseckaite R, Sheppard DM, Shourie S, Steenstra I, Van Eerd D, Amick BC 3rd. Effectiveness of Workplace Interventions in Return-to-Work for Musculoskeletal, Pain- Related and Mental Health Conditions: An Update of the Evidence and Messages for Practitioners. J Occup Rehabil. 2018 Mar;28(1):1-15.		
	In this video you will learn about how to optimize lifestyle in people with chronic pain. This video is intended for a public audience who want to learn more about the topic. In this video you will learn why work is a resource that should be maintained, even if working is not pain-free. This video is intended for a public audience who want to learn more about the topic.		
# Video & Link	Title	Description	Inspired in the article
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			Lindholm, L. et al. Does unemployment contribute to poorer health-related quality of life among Swedish adults?. BMC Public Health 19, 457 (2019).
25 https://youtu.be /QWwM9a100 Oc	P4Work Epidemiology of Neck Pain	In this video you will learn about the social and economic impact of neck pain and what are the statistics of neck pain on a global scale. This video is intended for a public audience who want to learn more about the topic.	Safiri S, Kolahi AA, Hoy D, Buchbinder R, Mansournia MA, Bettampadi D, Ashrafi- Asgarabad A, Almasi- Hashiani A, Smith E, Sepidarkish M, Cross M, Qorbani M, Moradi-Lakeh M, Woolf AD, March L, Collins G, Ferreira ML. Global, regional, and national burden of neck pain in the general population, 1990-2017: systematic analysis of the Global Burden of Disease Study 2017. BMJ. 2020 Mar 26;368:m791. Hallman DM, Holtermann A, Dencker-Larsen S, et alAre trajectories of neck–shoulder pain associated with sick leave and work ability in workers? A 1-year prospective studyBMJ Open 2019:9:e022006.

# Video & Link	Title	Description	Inspired in the article
26 https://youtu.be /frMTiNSf7P4	P4Work How to reduce Work- related Neck Pain	In this video you will learn about what physical exercises can be performed using a rubber band in order to reduce neck pain. This video is intended for a public audience who want to learn more about the torsic	Parikh P, Santaguida P, Macdermid J, Gross A, Eshtiaghi A. Comparison of CPG's for the diagnosis, prognosis and management of non- specific neck pain: a systematic review. BMC Musculoskelet Digord 2010 Feb
27 https://youtu.be /yIqUyw526M o	P4Work Is working good for you? (1): Health, work, and wellbeing	In this video you will learn about how work, health, and wellbeing may influence each other. This video is intended for a public audience who want to learn more about the topic.	Disord. 2019 Feb14;20(1):81.Waddell G, BurtonAK. Is work good foryour health and well-being? The StationeryOffice, London, UK.(2006) ISBN9780117036949
28 <u>https://youtu.be</u> <u>/tIy6mqMHZh</u> g	P4Work Is working good for you? (2): Unemployment and health	In this video you will learn about how unemployment can actually influence our mental and physical health. This video is intended for a public audience who want to learn more about the topic.	Waddell G, Burton AK. Is work good for your health and well- being? The Stationery Office, London, UK. (2006) ISBN 9780117036949
29 https://youtu.be /qKNZT3RuCa 0	P4Work Is working good for you? (3): Employment and health	In this video you will learn about the benefits that meaningful employment has on our health. This video is intended for a public audience who want to learn more about the topic.	Waddell G, Burton AK. Is work good for your health and well- being? The Stationery Office, London, UK. (2006) ISBN 9780117036949
30 https://youtu.be /ywtIBLsoQHg	P4Work Is working good for you? (4): Re- employment and health	In this video you will learn about the therapeutic effect of getting back into the workforce after a period of unemployment.	Waddell G, Burton AK. Is work good for your health and well- being? The Stationery Office, London, UK.

# Video & Link	Title	Description	Inspired in the article
		This video is intended for a public audience who want to learn more about the topic.	(2006) ISBN 9780117036949
31 https://youtu.be /wLuhGLFtelw	P4Work Is working good for you? (5): Therapeutic effect for Musculoskeletal Pain	In this video you will learn about the benefits of employment and re- employment for people with musculoskeletal pain and why work should be considered therapeutic. This video is intended for a public audience who want to learn more about	Waddell G, Burton AK. Is work good for your health and well- being? The Stationery Office, London, UK. (2006) ISBN 9780117036949

want to learn more about the topic.