**Aalborg Universitet**

# European knowledge alliance for innovative measures in prevention of work-related musculoskeletal pain disorders (Prevent4Work Project)

*Protocol for an international mixed-methods longitudinal study*

Bellosta-López, Pablo; Domenech-Garcia, Victor; Palsson, Thorvaldur; Christensen, Steffan Wittrup McPhee; de Brito Silva, Priscila; Langella, Francesco; Berjano, Pedro; Schlott Jensen, Palle; Riis, Allan; Baroncini, Alice; Blasco-Abadía, Julia; Jiménez-Sánchez, Carolina; Calvo, Sandra; Jaén-Carrillo, Diego; Herrero, Pablo; Høgh, Morten Sebastian; Prevent4Work Study Group

# 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

Pablo Bellosta-López [ORCID],[1] Victor Domenech-Garcia [ORCID],[1] Thorvaldur Skuli Palsson [ORCID],[2] Steffan Wittrup Christensen,[2,3] Priscila de Brito Silva [ORCID],[3] Francesco Langella [ORCID],[4] Pedro Berjano,[4] Palle Schlott Jensen,[3] Allan Riis,[3] Alice Baroncini,[4] Julia Blasco-Abadía,[1] Carolina Jiménez-Sánchez,[1] Sandra Calvo,[1] Diego Jaén-Carrillo,[1] Pablo Herrero [ORCID],[5] Morten Hoegh,[2] On behalf of the 'Prevent4Work' Study Group

**Correspondence to**
Dr. Victor Domenech-Garcia;
vdomenech@usj.es

## 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and prevention of work-related MSK pain do not consistently integrate current evidence-based knowledge and seem to be outdated.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 (1) risk factors associated with the prevalence of work-related MSK pain, (2) predictive factors for new events of work-related MSK pain in the short term and (3) 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 (ie, cross-sectional design) with follow-up after 3 and 6 months (ie, prospective–predictive design). Throughout the first phase (0–3 months), all participants will be offered to self-enrol 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'

### Strengths and limitations of this study

► Large multicentre study examining risk factors associated with work-related musculoskeletal (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.

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 P4W official channels.

## INTRODUCTION

Work-related musculoskeletal (MSK) pain refers to pain related to or leading to work-related 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

1

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 (1) physical factors (eg, manual handling, working in awkward postures, repetitive work and working at high speed), (2) individual factors (eg, stress exposure, health believes, beliefs about pain, sleep quality, social support), (3) contextual factors (eg, workplace design and organisation), and (4) sociodemographic factors (eg, level of education, age).[5]

The incidence and prevalence rates of work-related MSK pain are increasing worldwide, which may indicate a suboptimal effect of contemporary approaches for its management.[6] Insufficient implementation of evidence-based practice might be the primary contributor,[7] although outdated education of healthcare professionals and low-value treatments are also barriers for optimal management of work-related MSK pain.[8 9]

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 pain[11] 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 high-quality 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) that has recently been developed to detect populations at high risk of suffering work-related MSK pain.[13] Moreover, innovative educational programmes will be introduced, and adaptive mobile interactive digital platforms, capable of delivering evidence-based information and collect data, will be continuously developed (online supplemental table 1).

The research-specific aims of the P4W project are (1) to identify risk factors associated with the prevalence and/or the incidence of work-related MSK pain, (2) to evaluate the predictive capacity of the P4W questionnaire for new events of work-related MSK pain in the short term (ie, 3 and 6 months), (3) 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 well-being of people with chronic pain.[14] Additionally, there are insufficient data on how/if the COVID-19 pandemic causes new events
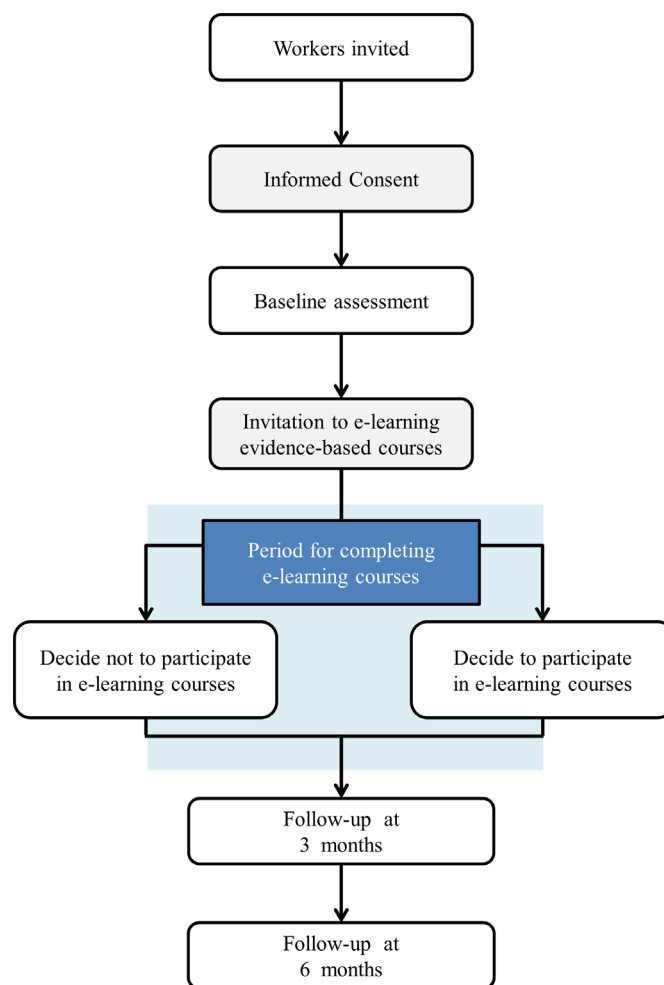


**Figure 1** Study timeline design.

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 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 (ie, cross-sectional study design) with follow-up at 3 and 6 months (ie, prospective–predictive study design). Throughout the first phase (0–3 months), all participants will be offered to self-enrol 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).

### 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.

### 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 organisation 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 organisations 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 are 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-anonymised, so it is impossible to relate the physical person to their data directly. For processing and exporting purposes, all data will be conveniently anonymised in a way that each data record is generated with a unique identifier that is not possible to relate to the physical person and their personal information.

All the measures will be conducted to comply with European Union's General Data Protection Regulation[17] and implemented following recommended guidelines.[18 19]

### 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 (online supplemental table 2). The

**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 |
|---|---|
| Baseline | ► P4W survey<br>  – Individual factors<br>  – Job demands<br>  – Lifestyle<br>  – MSK pain history<br>  – COVID-19<br>  – Pain beliefs<br>  – Work-related MSK pain training experience and interests<br>► P4W questionnaire |
| 3-month and 6-month follow-up | ► P4W follow-up survey<br>  – Verification of same job position<br>  – Verification of e-learning course participation<br>  – Lifestyle<br>  – MSK pain history<br>  – COVID-19<br>  – Pain beliefs |

MSK, musculoskeletal; P4W, Prevent4Work.

videos were developed in English and Spanish languages, with Italian or Danish subtitles and are publicly available at https://p4work.com/results/ (retrieved on 31 March 2021). For further analysis, all participants who have been invited to take the courses will be classified based on their interaction with the animated videos as: (1) no participation at all, (2) visualisation of videos in isolation/starting, but not finishing an e-learning course, (3) completion of one or more entire learning courses.

### Outcome measures

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

### Baseline

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

*Section 1*: this section will collect sociodemographic and personal information such as age, sex, weight, height, education level, job position and seniority.

*Section 2*: 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'.

*Section 3*: this section will collect information about lifestyle (physical activity out of work, sleep quality and

quantity), medical history of MSK pain (including onset, for example, 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 Questionnaire[21] proposed by the WHO. 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 two 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 nine body regions in the original scale will be reduced to four (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 pain[15] by using supplementary ad hoc questions.

*Section 4*: information about beliefs related to the cause and treatment of pain is 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).

*Section 5*: 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]

*P4W questionnaire*: 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 (1) a specific question to ensure the participant is performing the same job and type of work as baseline level, (2) a specific self-reported question related to the participation in e-learning courses, (3) 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 (4) the Pain Beliefs Questionnaire.

Data from the 3-month follow-up will be used to evaluate any potential change in pain beliefs, while 6-month follow-up will be used to test the short-term prediction 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 1500 workers to meet the European Commission requirements and analyse 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 alpha 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 regard 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 per-protocol 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.

**Author affiliations**

¹Department of Physiotherapy, San Jorge University, Villanueva de Gallego, Spain
²Department of Health Science and Technology, Aalborg University, Aalborg, Denmark
³Department of Physiotherapy, University College of Northern Denmark, Aalborg, Denmark
⁴Orthopedic and Traumatology, IRCCS Galeazzi Orthopedic Institute, Milan, Italy
⁵Physiatry and Nursing, Zaragoza University, Zaragoza, Spain

**Twitter** Victor Domenech-Garcia @_Victordomenech, Thorvaldur Skuli Palsson @tspalsson, Steffan Wittrup Christensen @SW_Christensen and Priscila de Brito Silva @pribsilva

**Contributors** All authors contributed significantly to the design of this study protocol. PB-L, VD-G, TSP, SWC, PdBS, FL, PB, PH and MH contributed to the conception and planning of the study protocol. PB-L, VD-G, TSP, PS, AR, PB and MH contributed to the acquisition of the data for the work. PB-L, VD-G, TSP, SWC, PdBS, PSJ, FL, PB, AB, JB-A, CJ-S, SC, DJ-C, 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.

**Disclaimer** The funders did not have any role in this study.

**Competing interests** None declared.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Supplemental material** This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

**ORCID iDs**
Pablo Bellosta-López http://orcid.org/0000-0003-4750-9077
Victor Domenech-Garcia http://orcid.org/0000-0002-7007-0368
Thorvaldur Skuli Palsson http://orcid.org/0000-0002-4418-0133
Priscila de Brito Silva http://orcid.org/0000-0002-5879-3600
Francesco Langella http://orcid.org/0000-0002-8639-8480
Pablo Herrero http://orcid.org/0000-0002-9201-0120

## REFERENCES

1  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:e032668.
2  Chang Y-F, Yeh C-M, Huang S-L, et al. Work ability and quality of life in patients with work-related musculoskeletal disorders. *Int J Environ Res Public Health* 2020;17. doi:10.3390/ijerph17093310. [Epub ahead of print: 09 May 2020].
3  de Kok J, Vroonhof P, Snijders J. 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/Work-related_MSDs_prevalence_costs_and_demographics_in_the_EU_report.pdf
4  Parent-Thirion A, Biletta I, Cabrita J. 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_document/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
7  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:S57–64.
8  Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet* 2018;391:2368–83.
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;32:800–16.
10 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;44:25–36.
11 Vargas-Prada S, Coggon D. Psychological and psychosocial determinants of musculoskeletal pain and associated disability. *Best Pract Res Clin Rheumatol* 2015;29:374–90.
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;154:856–63.
13 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:e043800.
14 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:e899.
15 Cipollaro L, Giordano L, Padulo J, et al. Musculoskeletal symptoms in SARS-CoV-2 (COVID-19) patients. *J Orthop Surg Res* 2020;15:178.
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;335:806–8.
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). *OJEU* 2016;119.
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-orientaciones-procedimientos-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-de-tratamiento.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;73:229–36.

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:e000206.

22 Hays RD, Martin SA, Sesti AM, *et al*. Psychometric properties of the medical outcomes study sleep measure. *Sleep Med* 2005;6:41–4.

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. *J Pain* 2009;10:517–26.

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;51:267–72.

25 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 P-O, 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;59:721–8.

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;70:57–62.

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;93:1615–24.