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Development of the Prevent for Work Questionnaire (P4Wq) for the assessment of musculoskeletal risk factors in the workplace: part 2—pilot study for questionnaire development and validation

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ABSTRACT

Objective The aim of this study was to develop a multifactorial, self-report questionnaire: Prevent for Work Questionnaire (P4Wq). The questionnaire is intended for screening for risk factors in work-related musculoskeletal disorders (WMSDs).

Design Data were collected from otherwise healthy workers employed in three service areas at a specialist hospital in Italy: healthcare, administration and ancillary services.

Setting and participants In all, 115 participants were enrolled (67% women; average age 41.5±9.94 years). The content of the tool for WMSDs was derived from three participation rounds of analysis involving a select group of experts who identified the questionnaire domains and items. Participants responded to 89 items in addition to the EuroQol 5 Dimensions Questionnaire (EQ-5D-5L), Fear-Avoidance Beliefs Questionnaire (FABq) and Oswestry Disability Index (ODI). The proportion of missing data and the distribution of responses were analysed for each item. Items with a discrimination index >0.40 and an interitem correlation <0.80 were retained. Factor analysis was performed using the VARIMAX rotation method, factor extraction, and identification, assignment of items to subscales, and assignment of scores to items. Internal consistency, reliability, construct validity and face validity were also assessed.

Results A total of 52 items were included in the factor analysis and four subscales identified: Physical Stress Subscore (six items); Mental Stress Subscore (six items); Job Satisfaction Subscore (four items) and Kinesiophobia/Catastrophizing Subscore (four items). The items in the final questionnaire version had a factor loading >0.7. The questionnaire consisted of 20 items with good internal consistency (Cronbach's alpha 0.81–0.91), reliability (weighted kappa coefficient 0.617–1.00), good construct

validity (EQ-5D-5L, r=−0.549, p<0.001; ODI, r=0.549, p<0.001; FABq work, r=0.688, p<0.001) and satisfactory face validity (universal validity index 96.04%).

Conclusion The P4Wq is a 20-item, multifactorial self-report risk assessment questionnaire. It may provide a useful tool for screening for WMSDs by specifically addressing back disorders. It investigates risks for individual workers and may inform educational programmes and preventive strategies tailored to a worker's needs.

Trial registration number NCT04192604

INTRODUCTION

Work-related musculoskeletal disorders (WMSDs) refer to damage to muscles, bones, joints and soft tissues associated with exposure to risk factors in the workplace.[1] WMSDs

range from mild, transitory disorders to chronic conditions if they persist for more than 12 weeks.[2] The European Agency for Safety and Health at Work (EU-OSHA) states that WMSDs are an increasing burden for Western societies.[3] For example, the Sixth European Working Conditions Survey reported a twofold increase in WMSDs of the spine and upper limbs in the last decade, accounting for half of employees' complaints.[4] In Europe, WMSDs are the most frequent occupational disorder and a major driver of healthcare costs.[3] WMSD-related costs are estimated at 2% of the gross domestic product in the European Union (EU)[5] and 50% of the costs of all work-related health issues.[6] In addition, WMSDs are responsible for half of the days of absenteeism lasting for more than 3 days, 49% of absenteeism lasting 2 weeks or more, and about 60% of cases of permanent work disability.[7]

WMSDs refer to musculoskeletal disorders in which multiple factors related to work activity, workplace environment and worker performance contribute to a varying extent to pain and disability. Physical stressors,[8] work stress, pain beliefs and sleep disturbances all seem to play a key role in the development of WMSDs,[9] loss of work productivity and absenteeism.[10] Research models have shown that stressful work environment,[11] mental stress[12] and fear-avoidance are closely linked to work-related disability and its progression to chronicity.

According to the EU-OSHA,[3] successfully managing WMSDs relies on prevention, early intervention and promotion of good musculoskeletal health in the workplace. The earlier the problem is identified, the better it can be addressed in clinical practice. A tool that integrates a multifaceted model seems ideal for combining the strengths of medicine, public health and psychology to optimise early diagnosis and management of WMSD and to identify operational steps in the prevention of WMSDs.[13]

Current medical evidence suggests that clinical interventions can reduce disability and absenteeism related to WMSDs.[14] A multidisciplinary approach can provide a critical starting point for achieving good outcomes.[15] Early diagnosis, psychosocial interventions,[16] workplace factor management[17] and education in preventing musculoskeletal pain[18] have reduced the incidence of WMSDs and related absenteeism.

The literature suggests that the risk of developing WMSDs and their progression to chronicity may be captured by a questionnaire investigating physical and psychosocial domains, including a biopsychosocial model of disease and fear-avoidance components of chronic pain.[19] With this in mind, the primary aim of this study was to develop a multifactorial self-administered questionnaire (Prevent for Work Questionnaire (P4Wq)) to investigate risk factors for WMSDs. The secondary objective was to compare the psychometric properties of the P4Wq against previously developed questionnaires to determine the construct behaviour of its final version. The psychometric properties of pain/discomfort, anxiety and depression were tested using the EuroQol 5 Dimensions Questionnaire (EQ-5D-5L),[20] while fear-avoidance behaviour was tested with the Fear-Avoidance Beliefs Questionnaire (FABq).[21]

METHODS
Study setting and population
This pilot study was conducted on behalf of the Prevent for Work Project funded by the European Commission within the EU Erasmus+ Programme. The study's primary aim was to develop a multifactorial, self-report risk assessment questionnaire for WMSDs and assess its psychometric properties. The sample size was set at 115 participants according to a previous study on the same topic.[22] The study was conducted at the IRCCS Istituto Ortopedico Galeazzi (IOG), Milan, Italy. The IOG is a research hospital that provides specialised, advanced orthopaedic care. It employs more than 1000 workers engaged in a variety of physically demanding tasks that may cause physical discomfort or pain.

Inclusion criteria were: ability to read and understand Italian and at least 1 year of work at the IOG. Exclusion criteria were: previous surgery for musculoskeletal disorders, musculoskeletal conditions (eg, fibromyalgia, arthritis, ankylosing spondylitis) or others that result in lasting disability or absence from work. The study participants worked in one of three areas: healthcare (physicians, nurses, radiology technicians, physiotherapists), administration (laboratory researchers, concept employees, video terminal workers), other ancillary services (maintenance, neurophysiopathology or orthopaedic technicians). Enrolment for each worker category was done using convenience sampling and interrupted when it reached 40% of the total sample; this was done to limit maximum possible inhomogeneity (of the whole cohort) and not exceed the proportions 40%–40%–20%.

This study followed the standards and criteria defined by the Strengthening the Reporting of Observational Studies in Epidemiology statement: guidelines for reporting observational studies.[23] The questionnaire development process began with a literature review and a Delphi study to identify domains and items for the pilot study.[19] PBerjano and FL designed the project for P4Wq development by following standards and criteria defined by the Consensus-based Standards for the selection of health Measurement INstruments guidelines for content validity evaluation of patient-reported outcome measures (PROMs).[24] Figure 1 illustrates parts one and two of the workflow of questionnaire development.

Content validity
In January 2020, a literature review was conducted to identify previously described risk factors and diagnostic and prognostic tools to assess WMSDs and their risk factors. The study group first identified all possible aspects needed to develop an evidence-based WMSDs risk assessment questionnaire: demographics, socioeconomic

Process Development Prevent 4 Work questionnaire
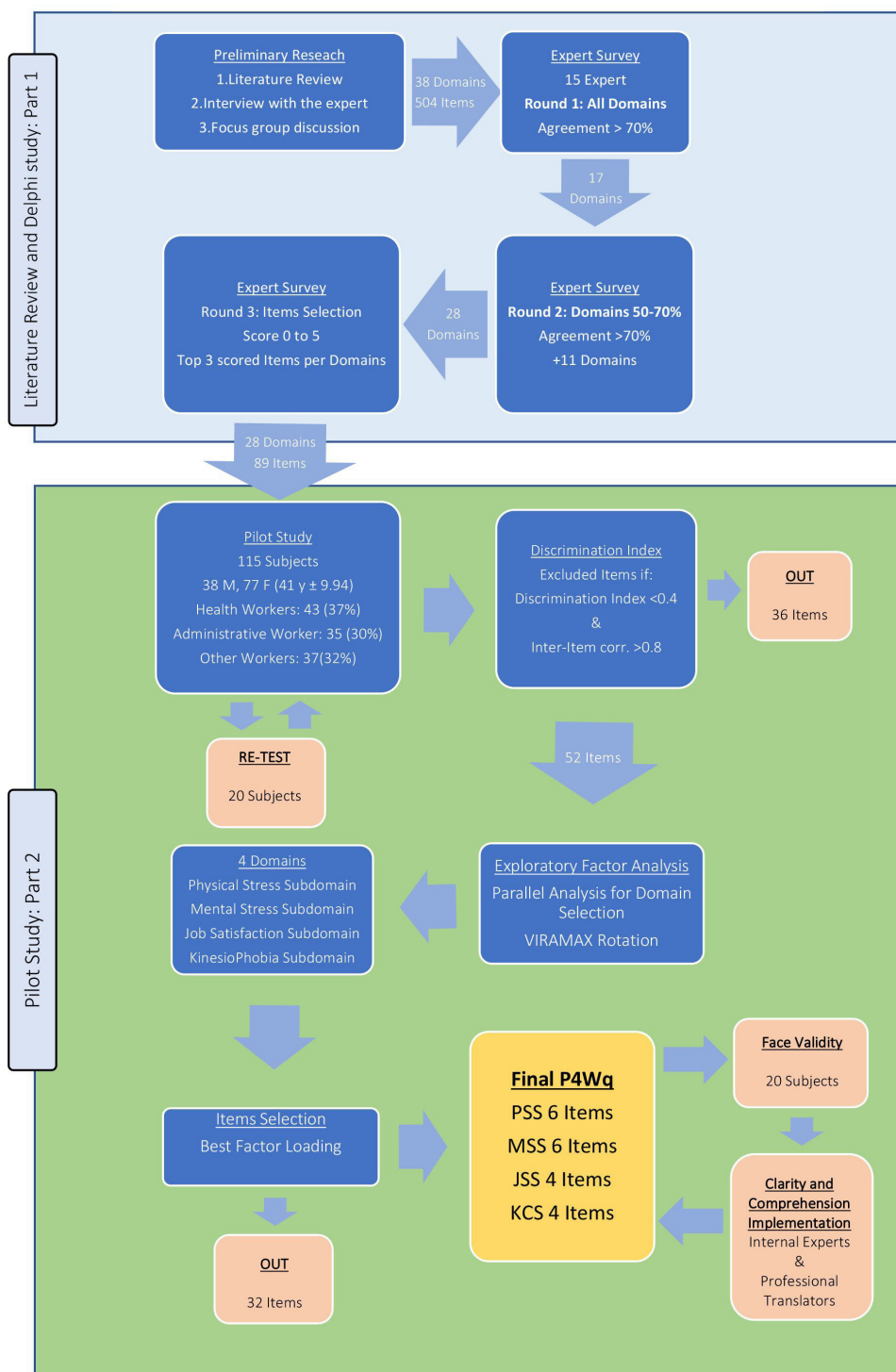
Figure 1 Overview of the workflow of the literature review and the Delphi process for the pilot study. JSS, Job Satisfaction Subscore; KCS, Kinesiophobia/Catastrophizing Subscore; MSS, Mental Stress Subscore; PSS, Physical Stress Subscore.

environment, health status, job position and quality of life. This identified questionnaires for the evaluation and stratification of the population based on the quality of life, disability and work-related pain beliefs.

A Delphi group of 15 experts in WMSDs was formed to define appropriate domains and items identified in the initial literature research. The initial WMSDs risk assessment questionnaire was developed based on 89 selected items in 28 domains that covered two factors.[19] The items and domains identified in the expert analysis moved into the pilot study phase after full approval of the contents by the labour unions, which then revised and approved the questionnaire and its domains before the pilot study was started.

Procedures

The pilot study participants completed four questionnaires (Generic health status score: EQ-5D-5L[25]; back pain disability: Oswestry Disability Index (ODI)[26 27]; Pain-related fear: FABq[28]), and the items identified for P4Wq development. Responses to the items on the new questionnaire were: never, rarely, sometimes, often or always. Each response was scored from 0 to 4 as follows: 0—never, 1—rarely, 2—sometimes, 3—often and 4—always. Inversion scoring was applied to the identified items. Participants were excluded if more than 50% of their responses were missing. The test–retest at 2 weeks (±1 week) was conducted with 20 randomly selected participants. Written informed consent was requisite for participation in the study.

Statistical data analysis was performed using SPSS (IBM Corp, released 2011, IBM SPSS Statistics, V.20.0). Results are expressed as average ±SD and/or 95% CI. Level of significance was set at p<0.05.

Structural validity

Only items with a response rate >50% were considered for the procedure. Based on the data collected, the index of discrimination was calculated for all items. The discrimination index was estimated based on the correlations between each item and the overall result of the questionnaire. Items with a discrimination index >0.40 and an interitem correlation <0.80 were entered in the factor analysis.

Bartlett's test of sphericity and Kaiser-Meyer-Olkin (KMO) tests were used to assess adequate sample composition. The dimensionality of the questionnaire was evaluated by conducting an exploratory factor analysis using the VARIMAX method of orthogonal rotation. VARIMAX rotation was used to improve data suitability for factor analysis. Furthermore, a parallel analysis was conducted to set the correct number of domains matching our results with parameters from a random data eigenvalue generator. The number of final factors retained was the number of eigenvalues larger than the corresponding randomly generated eigenvalues.[29] The final version of the questionnaire was composed of items with higher factor loadings within the subscores.

Internal consistency

Internal consistency was examined by testing the interitem correlation matrix and calculating Cronbach's α for the whole questionnaire and the single subscores once identified. When internal consistency was low (α<0.70), the reliability was recalculated after removing the items that reduced consistency. A Cronbach's α of 0.7–0.9 was considered acceptable.

Reliability

Test–retest reliability was performed to assess the stability of item response after 2 weeks±1 week follow-up in 20 randomly selected participants. To assess the reliability between Likert-like item responses, linear weighted kappa

statistics was used. The levels of kappa statistics were: 0.00<K<0.20 poor or slight agreement; 0.21<K<0.40 fair; 0.41<K<0.60 moderate; 0.61<K<0.80 substantial or good; 0.81<K<1.00 very good or perfect.

Hypotheses testing for construct validity

The resulting P4Wq was the sum of all selected items, each of which scored from 0 to 4. The final step in questionnaire development was the assessment of its convergent validity. The study group expected to find a significant correlation between the P4Wq and its subscores for indicators of quality of life (EQ-5D-5L), disability (ODI) and work-related pain (FABq work). Spearman's rank correlation or Pearson's correlation were applied to test these hypotheses. A significant although moderate correlation is desirable to establish the new questionnaire as a different tool that expands information on the population.[30]

The ODI[31] emerged as the most commonly recommended specific outcome measure for spinal disorders. This self-report questionnaire is composed of ten topics investigating pain intensity, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality and ability to travel. Each item is scored on a scale from 0 to 5. All item scores are summed, then multiplied by two to obtain the total ODI (range 0–100). Zero denotes no disability and 100 the maximum disability possible.

In 1993, Waddell et al[21] developed an FABq to estimate, from a biopsychosocial perspective, how physical activity and work can affect low back pain. The FABq is the sum of 11 items scored from 0 to 6. Two subscores assess fear-avoidance beliefs about physical activity and work, scored from 0 to 36 and 0 to 66, respectively.

The EQ-5D-5L[20] was developed as a standardised tool for measuring generic health status. It has been widely used in scientific research for health surveys, clinical studies, economic evaluation and clinical outcome assessment. The instrument has two components: health state description and evaluation. The report is based on five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is scored from 0 to 4. The health status evaluation section estimates overall health status graded on a visual analogue scale (VAS) from 0 to 100.

Face validity

Face validity was focused on the instructions, the medical history section, the 20 items of the P4Wq and responses to the questionnaire items. Assessment was performed 6 months after the first round of the full set of item collection. Face validity was assessed involving 20 randomly selected participants. Two separate Likert-like scales were used to evaluate clarity and comprehension. Clarity was evaluated on a 5-point scale from 1 (not clear at all) to 5 (very clear), and comprehension was evaluated on a similar scale from 1 (totally incomprehensible) to 5 (easy to understand). The face validity index was the average index value of these indexes. The results were then

Table 1 Study sample demographics

Characteristic	N=115 (%)
Healthcare	43 (37.4)
Administration	35 (30.4)
Ancillary	37 (32.2)
Age, years	41±9.94
Women no. (%)	77 (67)
ODI	7.70±7.93/100
FABq	26.65±21.87/66
EQ-5D-5L	81.19±14.75/100
Mobility	0.19±0.45
Self-care	0.08±0.30
Activity	0.28±0.48
Pain	0.91±0.79
Anxiety	0.39±0.63.
P4Wq	26.07±12.25/80
PSS	11.44±6.46
MMS	6.56±4.05
JSS	4.51±3.0
KCS	3.56±3.42

Administration, laboratory researchers, concept employees, video terminal workers; EQ-5D-5L, EuroQol 5 dimensions generic health status; FABq, Fear-Avoidance Beliefs Questionnaire; Healthcare, physicians, nurses, radiology technicians, physiotherapists; JSS, Job Satisfaction Subscore; KCS, Kinesiophobia/Catastrophizing Subscore; MSS, Mental Stress Subscore; ODI, Oswestry Disability Index; PPS, Physical Stress Subscore; P4Wq, Prevent for Work Questionnaire.

converted into percentage between 0 (totally unclear or incomprehensive) and 100% (clear or understandable). According to Polit et al[32] a face validity index >80% is considered satisfactory. The time to complete the new questionnaire was recorded for each participant.

Patient and public involvement
Patients were not involved in the design and conduct of this research. Priorities, experience and preferences of the target population (ie, workers) were not considered forming the aims, data analysis or dissemination of results. We intend to disseminate the main results of this research and will seek patient and public involvement in the development of an appropriate method of dissemination.

RESULTS
Pilot study
Participant characteristics
A total of 162 individuals gave their consent to participate in the study: 47 were excluded because of missing documentation or a response rate <50% (29.1%). Analysis of the missingness pattern revealed no significant differences. In all, 115 hospital employees (70.9%) were enrolled in the study: 38 (33%) men and 77 (67%) women, average age 41±9.94 years. The sample population breakdown was 43 (37.4%) healthcare workers, 35

(30.4%) administrative workers and 37 (32.2%) other workers. Table 1 presents the sample demographics.

Structural validity
The index of discrimination was ≥0.40 in 52/89 initial questionnaire items, which were used in the next validation step (table 2 and figure 1).

Bartlett's test of sphericity and the KMO tests showed adequate sample composition of the items for the factor analysis. After exploratory factor analysis, the parallel analysis identified four factors. For attribution of the items to the factors, the VARIMAX method of orthogonal rotation was used to minimise cross-loading and obtain uncorrelated factor structures. Factor analysis confirmed that the questionnaire was consistent with the biopsychosocial model of interpretation of risk factors on four distinct subscores. After evaluating the content of the subscore items, the study group named them: Physical Stress Subscore (PSS), Mental Stress Subscore (MSS), Job Satisfaction Subscore (JSS) and Kinesiophobia/Catastrophizing Subscore (KCS). The final version included the items with the best factor loading that allowed preserving the weight of each subscore. The P4Wq was composed of 20 items in all (23.d; 24.c; 23.a; 25.a; 27.b; 24.d; 18.d; 16.a; 18.a; 16.b; 18.d; 16.a; 14.c; 16.c 18.a; 16.b; 22.b; 22.a; 22.c; 21.b) and comprising the PSS (six items: 23.d; 24.c; 23.a; 25.a; 27.b; 24.d), the MSS (six items: 18.d; 16.a; 14.c; 16.c 18.a; 16.b), the JSS (four items: 6.c; 12.b; 4.c; 10.b) and the KCS (four items: 22.b; 22.a; 22.c; 21.b) (table 3). Inversion scoring was applied to item 16.b. The total P4Wq score was the sum of all item scores. Each subscore can be calculated separately to obtain more detailed information. The mean P4Wq score was 26.07±12.25, the mean PSS was 11.44±6.46, the mean MSS was 6.56±4.05, the mean JSS was 4.51±3.0 and the mean KCS was 3.56±3.42.

Internal consistency
The reliability for the whole P4Wq and the individual subscales was tested by internal consistency assessment. Cronbach's alpha ranged from 0.81 to 0.91 (α_{P4Wq}=0.89; α_{PSS}=0.91; α_{MSS}=0.823; α_{JSS}=0.815; α_{KCS}=0.823), indicating good internal consistency and that the P4Wq and its subscores describe the same phenomenon.

Reliability
The mean test–retest reliability was good to perfect for all items. Weighted kappa coefficients ranged from 0.617 to 1.00 (table 3), while the average time between test and retest was 11 days (±3.79).

Hypotheses testing for construct validity
In the final development stage of the P4Wq, construct evaluation was assessed by convergent validity with previously validated questionnaires. In this sample, the mean±SD ODI was 7.70±7.93, the overall FABq 26.65±21.87, the FABq *Job* subscale 16.55±14.71, the FABq *Physical Activity* subscale 12.09±8.95, the EQ5 total 81.19±14.75, the EQ5 *Mobility* subscore 0.19±0.45, the EQ5 *Self-care* subscore 0.08±0.30, the EQ5 *Activity* subscore 0.28±0.48, the EQ5

Table 2 Interitem correlation matrix

Domains	Items	r_{it}
Quantitative work demands	1.a Do you have to work very fast?	0.425*
	1.b Is your workload unevenly distributed so it piles up?	0.393
	1.c How often do you not have time to complete all your work tasks?	0.281
Sensory work demands	2.a Does your work demand a great deal of concentration?	−0.080
	2.b Does your work demand your constant attention?	0.037
	2.c Does your work require a high level of precision?	0.076
Influence at work	3.a Do other people make decisions concerning your work?	0.066
	3.b Do you have a large degree of influence concerning your work?	0.116
	3.c Can you influence the amount of work assigned to you?	0.114
Possibilities for development at work	4.c Does your work give you the opportunity to develop your skills?	0.560*
	4.a Do you have to do the same thing over and over again?	0.432*
	4.b Can you use your skills or expertise in your work?	0.465*
Degree of freedom at work	5.b Can you take holidays more or less when you wish?	0.308
	5.a Can you decide when to take a break?	0.531*
	5.c Can you leave your work to have a chat with a colleague?	0.355
Meaning of work	6.a Is your work meaningful?	0.179
	6.b Do you feel that the work you do is important?	0.146
	6.c Do you feel motivated and involved in your work?	0.563*
Role conflicts at work	7.a Are contradictory demands placed on you at work?	0.346
	7.b Do you sometimes have to do things, which seem to you to be unnecessary?	0.453*
	7.c Do you do things at work, which are accepted by some people but not by others?	0.283
	7.d Do you sometimes have to do things, which ought to have been done in a different way?	−0.374
Social support at work	8.a How often do you get help and support from your colleagues?	0.522*
	8.b How often do you get help and support from your immediate superior?	0.393
	8.c How often is your immediate superior willing to listen to your work related problems?	0.336
Social relations at work	9.a Do you work isolated from your colleagues?	0.328
	9.b Is it possible for you to talk to your colleagues while you are working?	0.468*
Sense of community at work	10.a Is there a good atmosphere between you and your colleagues?	0.516*
	10.b Is there good cooperation between the colleagues at work?	0.584*
	10.c Do you feel part of a community at your place of work?**	0.580*
Insecurity at work	11.a Are you worried about becoming unemployed?**	0.520*
	11.b Are you worried about it being difficult for you to find another job if you became unemployed?	0.557*
	11.c Are you worried about having to give up your job for health reasons?	0.462*
Job satisfaction	12.a How pleased are you with your job as a whole, everything taken into consideration?	0.486*
	12.b How pleased are you with the people you work with?	0.584*
	12.c How pleased are you with your work prospects?	0.515*
General health	13.a I seem to get sick a little easier than other people.	0.440*
	13.b I am as healthy as anybody I know.	0.449*
	13.c I expect my health to get worse.	0.460*
	13.d I need to see doctor and take medicine on a regular basis.	0.447*

Continued

Table 2 Continued

Domains	Items	r_{it}
Mental health	14.a How much of the time during the past 4 weeks have you felt so down in the dumps that nothing could cheer you up?	0.529*
	14.b How much of the time during the past 4 weeks have you been a very nervous person?	0.476*
	14.c How much of the time during the past 4 weeks have you felt calm and peaceful?	0.475*
Vitality	15.a How much of the time during the past 4 weeks did you15.a have a lot of energy?	0.529*
	15.b How much of the time during the past 4 weeks did you feel worn out?	0.429*
	15.c How much of the time during the past 4 weeks did you feel tired?	0.300
Behavioural stress	16.a I have difficulty to relax or enjoy myself.	0.407*
	16.b I have not been able to stand dealing with other people.	0.439*
	16.c I have found it difficult to be happy.	0.477*
Somatic stress	17.a How much of the time during the past 4 weeks have you had stomach ache or stomach problems?	0.292
	17.b How much of the time during the past 4 weeks have you had a tight chest or chest pains?	0.266
	17.c How much of the time during the past 4 weeks have you had tension in various muscles?	0.327
	17.d How much of the time during the past 4 weeks have you had difficulty to sleep?	0.395
Cognitive stress	18.a How much of the time during the past 4 weeks have you had problems concentrating?	0.638*
	18.b How much of the time during the past 4 weeks have you had difficulty with remembering?	0.532*
	18.c How much of the time during the past 4 weeks have you had difficulty in taking decisions?	0.633*
	18.d How much of the time during the past 4 weeks have you found it difficult to think clearly?	0.553*
Sense of coherence	19.a I believe I can cope with most situations in life.	0.273
	19.b I feel that what I do in my daily life is meaningful.	0.385
	19.c I do not feel that I am able to influence my future to any great extent.	0.593*
Problem-focused coping	20.a Do you try to find out what you can do to solve the problem?	0.487*
	20.b Do you do anything to solve the problem?	0.518*
Kinesiophobia	21.a I'm afraid that I might injure myself if I exercise.	0.335
	21.b Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening.	0.447*
	21.c If I were to try to overcome it, my pain would increase.	0.460*
Catastrophizing	22.a I become afraid that the pain will get worse.	0.637*
	22.b I feel I can't go on.	0.544*
	22.c It's terrible and I think it's never going to get any better.	0.412*
Force exertion	23.a Do you in your work often have to lift heavy loads (more than 5 kg)?	0.531*
	23.b Do you in your work often have to pull or push heavy loads (more than 5 kg)?†	0.562*
	23.c Do you in your work often have to lift with the load far from the body?†	0.677*
	23.d Do you in your work often have to lift in an awkward posture?	0.629*
Dynamic loads	24.a Do you in your work often have to bend heavily with your trunk?†	0.526*
	24.b Do you in your work often have to twist heavily with your trunk?†	0.607*
	24.c Do you in your work often have to bent and twist with your trunk?	0.606*
	24.d Do you in your work often have to lift the arms above shoulder height?	0.612*

Continued

Table 2 Continued

Domains	Items	r_{it}
Static loads	25.a Do you in your work often have to work in a heavily bent posture for a prolonged time?†	0.426*
	25.b Do you in your work often have to work in uncomfortable postures?	0.627*
	25.c Do you in your work often have to work in a heavily twisted posture for a prolonged time?†	0.467*
	25.d Do you in your work often have to work in a squatting or stooping posture for a prolonged time?	0.424*
Repetitive loads	26.a Do you in your work often have to work in the same postures?	0.269
	26.b Do you in your work often have to always make the same movements with your trunk?	0.442*
	26.c Do you in your work often have to make small movements with hands/fingers at a high workpace?	0.115
Ergonomic environment	27.a Do you in your work often have to not enough room around you to perform your work properly?	0.468*
	27.b Do you in your work often have to difficulty in exerting enough force because of uncomfortable postures?	0.656*
	27.c Do you in your work often have to not enough room above you to perform your work without bending?	0.524*
Vibration	28.a Do you in your work experience noticeable mechanical vibrations or shocks?	0.562*
	28.b Do you carry vibrating tools during your work?	0.293
	28.c Do you drive vehicles during your work?	0.078

The initial pool of 89 items in 28 domains and their index of discrimination (item total) correlation coefficients (r_{it}) for each item after the pilot study.
*Items with a discrimination index >0.40.
†Interitem correlation >0.80. Items with a higher discrimination index were selected for factor analysis to avoid multicollinearity and to have two similar items in the final steps.

Pain subscore 0.91±0.79 and the EQ5 *Anxiety* subscore 0.39±0.63.

There was a statistically significant negative association between the P4Wq score and the indicator of quality of life—EQ-5D-5L—(r=−0.549, p<0.001) and a significant positive association between disability index—ODI—(r=0.549, p<0.001) and work-related pain—FABq work—(r=0.688, p<0.001) (figure 2). For the subscores there was a significant positive association between the KCS items and the EQ5-Pain Subdomain (22.a r=0.549, p<0.001; 22.b r=0.503, p<0.001), MSS items mostly associated with the EQ5-Anxiety Subdomain (16.b r=0.426, p<0.001; 16.c r=0.4516, p<0.001; 18.d r=0.436, p<0.001), PSS items mostly associated with the EQ5-Pain Subdomain (24.d r=0.333, p<0.001; 27.b r=0.302, p<0.001) and JSS items associated with EQ5-Activity (4.c r=0.360 and 6.c r=0.342, p<0.001) and the EQ5-Pain Subdomain (4.c r=0.244, p<0.001). This moderate although significant correlation provides good evidence for the scale's construct validity.

Face validity
The universal validity index was 96.04%, clarity was 95.61% and comprehension was 96.48%. The outcomes indicated consistent face validity results. One item from the KCS, formerly item #11, ('The most reliable way to prevent my pain from increasing is to make sure I don't make unnecessary movements'.) performed lower on face validity (universal validity index 92%) and so was improved in

the final version. In November 2020, the experts and two professional translators agreed on the final version via forward back translation (Italian to English≥English to Italian): 'I avoid unnecessary movements to prevent the pain from getting worse'. (*From the final original Italian version:* 'Evito movimenti non necessari per impedire che il dolore peggiori'.) The median time to complete the P4Wq was 3 min (table 3).

DISCUSSION
The 20-item P4Wq was developed and validated in this study. Its core construct is based on a biopsychosocial model of WMSDs. As suggested in a previous study,[19] this approach indicates that the conceptual model for developing a new risk assessment questionnaire for WMSDs should address physical and psychosocial factors.

STRUCTURAL VALIDITY
To identify hazardous situations that require ergonomic interventions, Hildebrandt *et al* designed a comprehensive tool to identify physical stressors in the workplace: the Dutch Musculoskeletal Questionnaire.[33] Based on global assessment of workload and other potentially hazardous working conditions, the P4Wq was developed to identify risk groups and to inform experts with data

Table 3 Factor analysis, item reliability and face validity for selected items

Subdomain	Item number and content	Kappa value (FV index %)	Domains 1	2	3	4
Physical Stress Subscore	**23.d Do you in your work often have to lift in an awkward posture? (#16—P4Wq)**	**0.860 (94.2)**	0.803			
	24.c Do you in your work often have to bent and twist with your trunk? (#17—P4Wq)	**0.771 (94.2)**	0.796			
	23.a Do you in your work often have to lift heavy loads (more than 5 kg)? (#15—P4Wq)	**0.828 (98.5)**	0.795			
	25.b Do you in your work often have to work in unconformable postures? (#19—P4Wq)	**0.867 (97.6)**	0.775			
	27.b Do you in your work often have to difficulty in exerting enough force because of uncomfortable postures? (#20—P4Wq)	**0.703 (94.2)**	0.746			
	24.d Do you in your work often have to lift the arms above shoulder height? (#18—P4Wq)	**0.919 (95.2)**	0.728			
	25.c Do you in your work often have to work in a heavily twisted posture for a prolonged time?	0.635	0.692			
	28.a Do you in your work experience noticeable mechanical vibrations or shocks?	1.000	0.650			
	25.d Do you in your work often have to work in a squatting or stooping posture for a prolonged time?	0.795	0.609			
	27.c Do you in your work often have to not enough room above you to perform your work without bending?	0.876	0.557			
	27.a Do you in your work often have to not enough room around you to perform your work properly?	0.856	0.533			
	26.b Do you in your work often have to always make the same movements with your trunk?	0.885	0.525			
	5.a Can you decide when to take a break?	0.706	0.474			
	1.a Do you have to work very fast?	0.767	0.406			
Mental Stress Subscore	**18.d How much of the time during the past 4 weeks have you found it difficult to think clearly? (#10—P4Wq)**	**0.850 (94.3)**		0.728		
	16.a I have difficulty to relax or enjoy myself. (#6—P4Wq)	**0.831 (94.7)**		0.651		
	14.c How much of the time during the past 4 weeks have you felt calm and peaceful? (#5—P4Wq)	**0.775 (95.7)**		0.645		
	16.c I have found it difficult to be happy. (#8—P4Wq)	**0.909 (94.6)**		0.641		
	18.a How much of the time during the past 4 weeks have you had problems concentrating? (#9—P4Wq)	**0.945 (97.1)**		0.615		

Table 3 Continued

Subdomain	Item number and content	Kappa value (FV index %)	Domains 1	2	3	4
	16.b I have not been able to stand dealing with other people. (#7—P4Wq)	**0.938 (94.7)**		0.611		
	18.c How much of the time during the past 4 weeks have you had difficulty in taking decisions?	1.000		0.610		
	18.b How much of the time during the past 4 weeks have you had difficulty with remembering?	0.881		0.598		
	14.a How much of the time during the past 4 weeks have you felt so down in the dumps that nothing could cheer you up?	0.794		0.550		
	20.b Do you do anything to solve the problem?	0.848		0.536		
	15.a How much of the time during the past 4 weeks did you15.a have a lot of energy?	0.781		0.516		
	14.b How much of the time during the past 4 weeks have you been a very nervous person?	0.853		0.509		
	20.a Do you try to find out what you can do to solve the problem?	0.923		0.485		
	15.b How much of the time during the past 4 weeks did you feel worn out?	0.807		0.465		
Job Satisfaction Subscore	**6.c Do you feel motivated and involved in your work? (#2—P4Wq)**	**0.617 (98.1)**			0.745	
	12.b How pleased are you with the people you work with? (#4—P4Wq)	**0.846 (96.6)**			0.745	
	4.c Does your work give you the opportunity to develop your skills? (#1—P4Wq)	**0.830 (96.6)**			0.711	
	10.b Is there good co-operation between the colleagues at work? (#3—P4Wq)	**0.816 (98.5)**			0.670	
	8.a How often do you get help and support from your colleagues?	0.659			0.663	
	4.b Can you use your skills or expertise in your work?	0.634			0.656	
	10.a Is there a good atmosphere between you and your colleagues?	0.831			0.652	
	12.c How pleased are you with your work prospects?	0.888			0.648	
	12.a How pleased are you with your job as a whole, everything taken into consideration?	0.820			0.644	
	7.b Do you sometimes have to do things, which seem to you to be unnecessary?	0.769			0.523	
	19.c I do not feel that I am able to influence my future to any great extent.	0.744			0.440	

Table 3 Continued

Subdomain	Item number and content	Kappa value (FV index %)	Domains 1	2	3	4
Kinesiophobia and Catastrophizing Subscore	**22.b I feel I can't go on. (#13—P4Wq)**	**0.779 (95.2)**				0.802
	22.a I become afraid that the pain will get worse. (#12—P4Wq)	**0.913 (95.7)**				0.796
	22.c It's terrible and I think it's never going to get any better. (#14—P4Wq)	**0.839 (94.2)**				0.777
	21.b Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening. (#11—P4Wq)	**0.813 (91.9)**				0.682
	21.c If I were to try to overcome it, my pain would increase.	1.0				0.676
	11.c Are you worried about having to give up your job for health reasons?	0.910				0.592
	13.d I need to see doctor and take medicine on a regular basis.	0.948				0.586
	13.c I expect my health to get worse.	0.804				0.510
	13.b I am as healthy as anybody I know.	1.000				0.488
	11.b Are you worried about it being difficult for you to find another job if you became unemployed?	0.837				0.478
	13.a I seem to get sick a little easier than other people.	0.817				0.457

Extraction method: Principal Component Analysis.
Rotation method: Varimax with Kaiser Normalisation.
Factor analysis results. Given in bold are the items included in the final version of the P4Wq and numeration (p<0.05). Kappa value: item reliability at 2 weeks±1 week follow-up. FV index %: face validity index, the average between clarity and comprehension expressed in percentage.
*Rotation converged in five iterations.
P4Wq, Prevent for Work Questionnaire.

to set priorities and apply educational and preventive actions for workers.

In addition to physical factors, the development and persistence of chronic pain correlate with psychological and social risk factors.[34] There is increasing evidence that psychosocial risk factors play a major role in developing, maintaining or progression to chronic WMSDs. For example, fear-avoidance and catastrophizing[35] behaviour are characteristic of patients with musculoskeletal disorders,[36] and questionnaires such as the Tampa Scale of Kinesiophobia[37] are a good predictor of disability and chronic back pain.[38] In addition, questionnaires that include the assessment of job stress and satisfaction or emotional and cognitive dimensions, such as the Copenhagen Psychosocial Questionnaire, seem to provide a comprehensive evaluation of more relevant factors at work.[39] The results of our pilot study laid the basis for the development of a questionnaire that includes assessment of physical factors, mental stress factors, working environment, kinesiophobia and fear-avoidance behaviour.

In their milestone 2003 study, Linton and Boersma presented a multifactorial approach to the detection of WMSDs: the Örebro Musculoskeletal Pain Questionnaire (ÖMPq). By integrating psychological variables, this instrument demonstrated good prediction of future absenteeism due to sickness.[40] Despite its widespread endorsement, several limitations were identified in the decades to follow. With our study we wanted to maintain a multifactorial approach to WMSDs while addressing some of the limitations of the original ÖMPq that later studies recognised, such as the lack of rigorous development,[41] non-validated modifications,[42] inconsistent wording and factor structure.[43]

Another critical aspect not to be underestimated is that there is no simple relationship between physical and psychosocial risk factors and musculoskeletal disorders. Recent evidence suggests that it is essential to apply a systematic approach to identifying these factors in the workplace and the specific problems of workers.[44] There is a well-known link between the incidence of WMSDs and the working environment, specifically for physical risk factors.[2] Furthermore, synergies between risk factors (eg, stress and work intensification) and psychosocial factors can contribute to the onset of such disorders. In addition to risk factors related to the working environment, the intrinsic aspect of workers not directly related to work may also contribute to WMSDs. Such
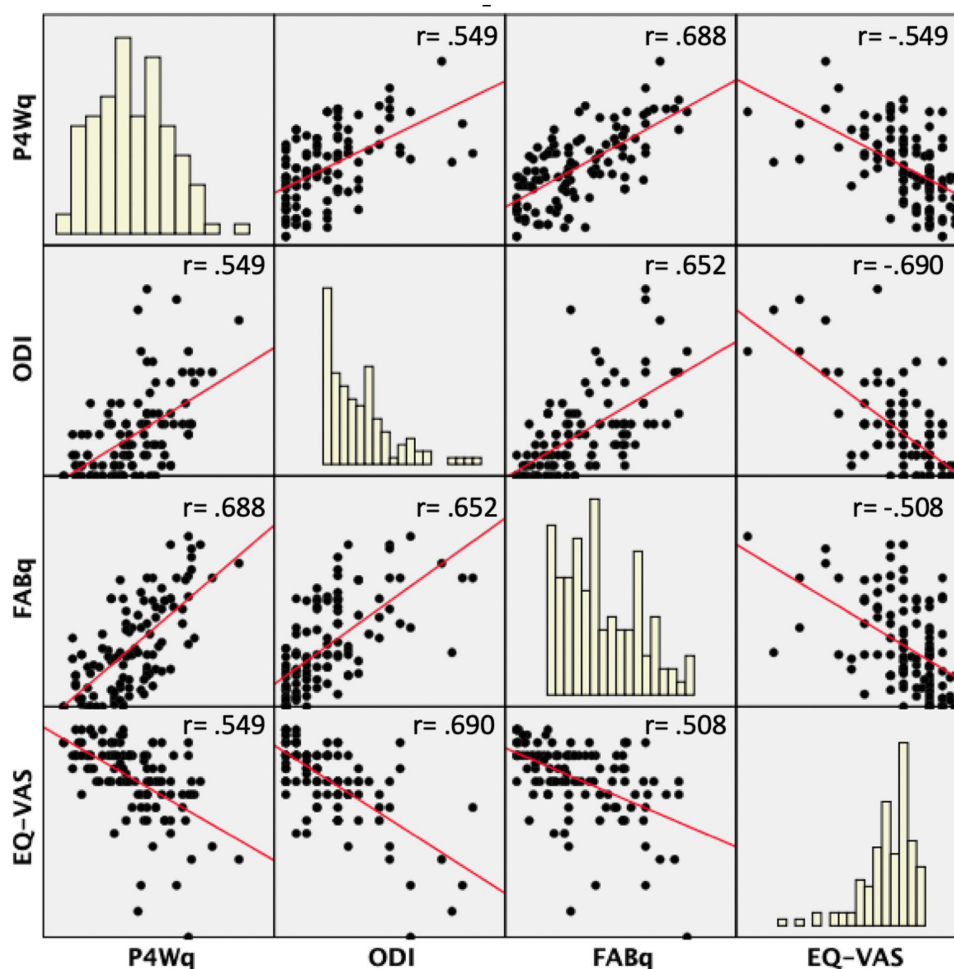
Figure 2 Pearson's correlation for a negative association with the indicator of the quality of life (EQ-5D-VAS (EuroQol Group General health status score-Visual Analogue Scale)) and a positive association with disability index (ODI (Oswestry Disability Index)) and work-related pain (FABq (Fear-Avoidance Beliefs Questionnaire)). The associations are statistically significant for all variables (two-tailed, p<0.001). P4Wq, Prevent for Work Questionnaire.

a wide variety of factors may explain the difficulties often encountered in taking a systematic approach to WMSDs and the best intervention to adopt. Furthermore, individual responses can vary widely. Based on a literature review and Delphi study, three groups of risk factors are: physical, psychosocial and individual factors.[19]

In this perspective, the 20-item questionnaire showed that its psychometric properties meet the minimum standards for PROMs set forth by the International Society for Quality of Life Research,[45] demonstrating good content validity, internal reliability consistency, construct validity and responsiveness. Factorial data analysis identified four subscales: PSS (six items), MSS (six items), JSS (four items) and the KCS (four items). The P4Wq is currently available in Italian (online supplemental appendix A) and English (online supplemental appendix B). Other translations are freely available online (https://p4work.com/results/).

In addition, structural validity showed that the psychological weight of workers was relevant. Healthcare workers are under continuous pressure and work in high complexity structures where the primary aim is to deliver high-quality care. Evaluation of the interaction between risk factors is

fundamental, especially in this group of workers, rather than focus on only one factor. For this reason, a high P4Wq score does not necessarily indicate that the worker experiences pain or disability due to a WMSD but rather that there is a theoretically increased risk of developing one in the future.

CONSTRUCT VALIDITY

The study indicated that the questionnaire is valid, applicable and can be useful in the analysis of risk factors for WMSDs. Comparative analysis between the P4Wq and validated questionnaires (ODI, FABq, EQ-5D-5L) identified a key correlation that provides strong evidence for its construct validity. The behaviour of the total P4Wq score showed a direct correlation with the ODI disability score and an inverse correlation with the EQ-5D-5L quality of life score. Workers scoring high on the P4Wq are at greater risk if they have a WMSD. The diagnostic, predictive and risk stratification capabilities of the P4Wq need to be explored in future studies. Based on the analysis in this sample, the P4Wq seems to overcome the floor effect of the ODI and the ceiling effect of the EQ-5D-VAS. This raises optimism for its ability to stratify otherwise healthy

workers and to detect WMSDs, which will be an area of focus for future studies. In addition, as a tool that stratifies risks, the P4Wq and collaboration between academia, work health-related institutions and health technology companies can lead to the development of innovative preventive strategies against WMSDs.

Methodological considerations and limitations

One limitation of this study is that the P4Wq involved employees at a single centre where most were healthcare workers. The aim of the instrument is to address generic issues in a variety of settings rather than to a specific healthcare centre. The construct validity of the P4Wq was evaluated using two questionnaires (ODI and FABq) that were developed to evaluate patients with back pain. It is possible, therefore, that the current validation process is to a lesser extent transferrable to WMSDs in other anatomical regions.

Nearly all participants were Caucasian and participated voluntarily in the study, which may have created a selection bias limiting generalisability. A further limitation is the inadequate sample size to evaluate test–retest reliability. A sample of 30 participants would be preferable for such purposes.[24] To date, the P4Wq has not been evaluated for its potential diagnostic and predictive capabilities in musculoskeletal disorders. This will be the focus of future studies. Also, further work is desirable to validate the questionnaire in other populations and languages. High-quality studies with a larger sample size and longer follow-up period are needed to consolidate the knowledge so far acquired, assess the predictive capabilities of the questionnaire and curtail some of the bias of the present study.

CONCLUSIONS

The aim of this study, derived from a literature review and a Delphi consensus, was to develop the P4Wq. The domains and items define a conceptual framework consistent with a biopsychosocial model of disease and the fear-avoidance components of chronic pain. The P4Wq has four subscales: PSS, MSS, JSS and KCS. It provides a concise measure of risk factors for work-related back disorders that have demonstrated good content validity, construct validity, internal consistency reliability and high face validity. For the methodological approach used and its intrinsic limitations, the questionnaire specifically assesses back disorders, and this aspect limits generalisability to all WMSDs. Further studies are needed to assess the ability of the P4Wq to predict WMSDs occurrence or progression to chronicity.

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