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Editorial

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We Need to Develop, Not Forget, Our Toxicological Knowledge

Considering chemical risk today may be of marginal interest, and some less benevolent scholars might belittle it as a form of scientific veteranism. Other issues are currently attracting the attention and commitment of occupational physicians (referred to as "competent" according to Italian law), i.e., biomechanical and psychosocial risks, Total Worker Health® programs, and biological hazards faced at the beginning of this decade during the COVID-19 pandemic.

We have also seen a contraction in the number and quality of publications in our scientific journals dedicated to toxicological issues. Given these undoubted facts, it is appropriate to fine-tune the issues that still represent an essential area of commitment for our Discipline. I will, therefore, try to briefly explain the reasons for this reflection with a necessary premise.

Careful and qualified regular environmental and biological monitoring practices appear essential to correctly quantify chemical risk. Only quantitative data provide objective bases comparable over time and in different work situations on which to develop health and prevention programs. Qualitative other different methods, often still used, cannot guarantee this, even if they are recognized and have a preparatory or complementary value if well-identified and conducted.

It is also in total harmony with Galileo Galilei's famous aphorism: "Measure what is measurable, make measurable what is not". As early as 1600, this aphorism foretold a way of doing science that was no longer based on subjective observation but on data provided by scientific instruments.

It appears difficult to dispute that the values of environmental and biological indicators measured in the occupational field are increasingly close to those measured in the living environment and in the general population groups not exposed. This results from the reduction of the former and the relative increase of the latter, resulting from the well-known eco-dispersion of many pollutants.

A result of no minor importance is that, for a complete, correct evaluation of exposures, the current action levels and the limit values proposed in the field of employment need to be revised. These are sometimes significantly above the measured values, thus creating grey areas in which appropriate decision-making guidelines must be revised.

It is therefore highly advisable to use the reference values together with them, i.e., those measured in the general population with a footnote: the difference between the two values tends to be increasingly blurred, also due to the lowering of the limit values, a sometimes drastic lowering and, as a matter of fact, also of objective difficulty or impossibility of measuring and verifying that they meet the quality standards in force (at least with the tools and methodologies currently available).

It cannot be forgotten that the trend above of the reduction in exposures should be confirmed over time, be demonstrated in all working realities (it is easy to infer the reference to tiny shops), and hopefully be so for the newly introduced chemical agents and the most innovative work cycles.

Another point worth considering is that the already mentioned current low levels of the indicators measured in the occupational field are generally higher than those of the general population. Thus, this testifies to exposure to the absorption of xenobiotics as worthy of study and control.

These considerations on the present and these hypotheses of research advancement for the future can only be made thanks to the same extraordinary progress recorded in analytical techniques and methods, progress concerning practically all the analytical areas of our interest, from spectrometry to gas chromatography, electron microscopy, analytical and immunological and molecular approaches. This should create the conditions:

- to have increasingly sensitive and informative dose indicators, coming to explore doses well below the critical or effective ones, thus allowing us to start and achieve some of our historical objectives;

- to put in place indicators of effect that are increasingly specific and early and therefore increasingly providing information on the mechanisms of action of toxic agents, ensuring a greater understanding of the pathologies related to them, at a stage in which their prevention is still possible.

Thanks to the commitment to multidisciplinary work and interdisciplinary permeability, with a certain optimism, we can foresee their greater availability and accessibility in a relatively short time. We will be able to do this if at least two conditions are met:

- the provision of adequate resources, certainly higher than the current ones, intended for innovative instrumentation essential for applied and translational research;

- the creation and development of facilities for the measurement of these new analytes that make them increasingly available, usable, and accessible.

Creating regional and national networks of the leading centers and offices of specialized sections of Occupational Medicine appears crucial to achieving these ambitious goals.

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La Medicina del Lavoro

Reviews, Commentaries, Perspectives

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Occupational Exposure to Benzene and Risk of Breast Cancer: Systematic Review and Meta-Analysis

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Keywords: Benzene; Breast Cancer; Meta-Analysis; Systematic Review; Occupational Exposure

Abstract

Introduction: *Benzene is a recognized carcinogen; however, its association with breast cancer is not well established. Hence, a meta-analysis of cohort and case-control studies was performed to determine the association between occupational benzene exposure and the risk of breast cancer.* **Methods:** *A systematic literature review identified 7573 publications from which 23 cohort and case-control studies were retained and evaluated using meta-analyses (random effects model). PRISMA guidelines were followed. Our protocol was registered in the PROSPERO database (Registration No. CRD42022379720). Study quality was assessed using a modified Newcastle-Ottawa scale (NOS).* **Results:** *The summary relative risk (RR) for ever-benzene exposure was 1.17 (95% CI=1.06-1.28, I2=38.6%,p=0.032, n=23 risk estimates); corresponding RR for cancer incidence and mortality were 1.17 (95% CI=1.05-1.29, I2=56.1%,p=0.003, n=16) and 1.09 (95% CI=0.86-1.38, I2<0.001%,p=0.96, n=10). However, heterogeneity was not detected for publication year (p-het=0.10), study design (p-het=0.78), study quality (p-het=0.06), and industry of employment (p-het=0.86). The RR for a high level of exposure showed a positive association with breast cancer 1.35 (95% CI=1.06-1.72, I2 =<0.001%,p=0.65, n=3) and (P-het=0.87). Publication bias was detected (p=0.03).* **Conclusions:** *The results of our meta-analysis indicate a positive association between occupational benzene exposure and an increased risk of breast cancer, particularly when exposed to higher levels of benzene. However, bias and confounding could not be excluded.*

1. Introduction

According to the 2022 GLOBOCAN database, breast malignancy is a leading cause of cancer incidence and mortality, with an estimated 2.3 million new cases accounting for 11.7% of all cancer cases worldwide. With 666,103 deaths reported in 2022, it serves as the fourth leading cause of cancer mortality globally [1]. The risk of breast cancer is affected by several factors, including aging, family history, reproductive history, genetics, and estrogen levels.

Although there is a firmly established correlation between lifestyle variables such as alcohol

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consumption, there is limited evidence that malignancy of the breast is also associated with exposure to several environmental carcinogens such as 1,3-butadiene, ethylene oxide (EtO), methylene chloride, benzene, and other solvents [2, 3]. The occupational setting is one of the primary sources of benzene exposure. Benzene is an aromatic hydrocarbon that may be found in natural reservoirs, industrial processes, and daily human activities. It is also utilized as a starting or intermediate material in chemical processes and manufacturing in several industries. Occupations reported to have the highest benzene exposure include chemical, manufacturing, steel, paint, shoes, rubber, textile, cleaning, electronics, leather, fur processing, and petroleum and crude-oil extraction and refining [4]. In addition, benzene exposure is observed among workers involved in the transportation of gasoline, service station workers, lab technicians, firefighters, workers in the printing and publishing industry, and other occupations with exposure to exhaust from motor vehicles [5]. At the workplace, the route of exposure to benzene is primarily through inhalation and dermal absorption [6-8].

Benzene has been categorized as a class 1 carcinogen in humans. The International Agency gives this classification for Research on Cancer (IARC) due to sufficient evidence in humans about benzene's association with leukemia, particularly acute myeloid leukemia (AML) [9-14]. Previous studies have shown that benzene exposure is linked to teratogenic effects and may lead to an increased risk of breast cancer due to mutations. Benzene and its byproducts may disrupt the endocrine system, leading to dysplasia and neoplastic transformation in the mammary gland. In its pure form, benzene is a colorless, highly flammable, and volatile liquid that has historically been used as an industrial solvent. Within humans, benzene's primary metabolites include benzene-oxide, hydroquinone, phenol, and catechol, all of which have been evaluated for their carcinogenic activity. The conversion of benzene to these metabolites is the most critical path accounting for benzene toxicity in humans [15-18].

Limited cohort and case-control studies investigating the association of benzene exposure and breast cancer have been published, providing inconsistent findings. It is challenging to isolate benzene exposure from external lifestyle or environmental factors because it usually occurs in conjunction with other chemicals in various occupations [19]. Even still, the health effects of benzene may best be studied in occupational settings where confounding variables may be limited, and dose and duration of exposure may be better measured. In addition, there is a lack of studies evaluating industrial occupations with sufficient dosage and duration of benzene exposure, and studies of female workers tend to be small [19-22].

This meta-analysis seeks to investigate the potential relationship between occupational benzene exposure and the incidence of breast cancer. The study employed a quantitative assessment approach, utilizing cohort and case-control studies.

2. Methods

2.1. Data Sources, Search Strategy

This systematic review and meta-analysis was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [23]. After building a study protocol, it was registered in the Prospective Registry of Systematic Reviews, PROSPERO database (Registration No. CRD42022379720).

The PECOS (Participants; Exposition; Comparators; Outcomes; Study Design) criteria was followed while conducting a comprehensive systematic review. The objective of this study was to include all publications that reported results on occupational exposure to benzene and the associated risk of solid tumors. All relevant publications quoted in the IARC Monograph on benzene exposure published in 2018 were included. In addition, a search of the PubMed, SCOPUS, and EMBASE (Ovid) databases was conducted on the association between occupational exposure to benzene and risk (incidence and mortality) of any solid cancer type by two independent researchers (MSS and MB). The first search was completed in December 2022 and then in April 2024 we updated it. Details of the overall project and results of other than breast cancer reported elsewhere [24, 25, 70].

A string for the search was created by using certain words or phrases (neoplasms * or carcinoma * or cancer * or malignant *) and (benzene * or benzol * or cyclohexa-1* or 3 5 triene * or 5-cyclohexatriene * or 5-cyclohexatriene *) [All Fields]). For this study, these, only studies reporting risk estimates for breast cancer were retained. (The complete search string is reported in Supplementary Table 1).

2.2. Eligibility Criteria

The goal of this study was to include all publications that reported relative risks (RRs) of breast cancer for occupational benzene exposure. For the systematic review, the literature search of titles, abstracts, and full-text publications was independently conducted by two authors (MSS and MB), with the goal of identifying occupational exposure to benzene among workers in a variety of jobs and industries. In order to select a study for this meta-analysis, the following inclusion criteria were established: (i) peer-reviewed industry-based cohort or case-control (including nested case-control within a cohort) studies of workers employed in industries and occupations in which benzene represents a major source of exposure such as petroleum industry (all phases: extraction, refining, distribution, gas station), shoemakers, paint production and painters, chemical industry, rubber industry, printing, laboratory workers; (ii) community-based case-control studies, if they reported results on benzene exposure (not on job/industry of employment). For the studies, the reference population was either an occupational-specific or a general population, not exposed to benzene. The outcome measures were either incident cases or deaths from breast cancer, predominantly among females (with 4 out of the 21 studies also reporting analysis for breast cancers among males). Studies reporting odds ratio (OR), standardized incidence ratio (SIR), standardized mortality ratio (SMR), risk ratio/relative risk (RR), hazard ratio (HR), including their 95% Confidence Intervals (CI), or sufficient data for their computational analysis were included.

Conversely, the exclusion criteria utilized for the systematic literature search included: (i) conference abstracts, letters, book chapters, descriptive, ecological, and cross-sectional studies, as well as systematic reviews or meta-analyses that did not mention or include analysis on benzene exposure; (ii) studies on non-solid tumors including leukemia, lymphoma or myeloma; (iii) studies on solid tumors and benzene not reporting OR, SIR, SMR, RR, HR or sufficient data to compute them. In instances where multiple publications referenced the same study population, the publication with the highest number of cases, or the one considered the most comprehensive, was included. To minimize the effects of confounding variables such as exposure to other chemicals or toxins, workers with occupational benzene exposure were only included if the study explicitly isolated benzene as the primary carcinogen. A flow diagram of the literature search and study selection process has been provided in Supplementary Figure 1.

Two sets of independent reviewers (MSS and MB) carefully examined the abstracts, titles, and full texts of the remaining studies. They then meticulously analyzed each study to extract pertinent data to advance the study's goals. Given the aforementioned inclusion and exclusion criteria, the two independent sets of researchers were in concordance with the studies selected for this meta-analysis.

2.3. Data Extraction

Utilizing a standardized template form, data was recorded independently by five authors (MSS, MB, DS, VD, and VS) on (i) author details, (ii) publication year, (iii) publication title, (iv) country/geographical location, (v) type of study design, (vi) period of employment, (vii) study's overall sample size, (viii) occupation and industry-type (with mixed industry defined as a combination of occupations with benzene exposure at work), (ix) type of cancer (including topography and histology), (x) workers' sex, (xi) ICD code associated with breast cancer, (xii) outcomes (incidence and mortality), (xiii) duration of benzene exposure (based on years of employment), (xiv) effects size measures including the relative risks (HRs/RRs/SMRs) for the cohort studies and the odds ratios (ORs) for the case-control studies and their corresponding 95% CI, (xv) number of outcome cases, (xvi) factors adjusted, such as but not limited to body mass index (BMI), smoking status, alcohol consumption, family history of breast cancer,

age at menarche/menopause, and exposure to other occupational solvents.

2.4. Quality Assessment

The study's quality metric was assessed by utilizing the original version of the Newcastle-Ottawa Scale (NOS) [26]. For a total score of 9 (for case-control studies) and 10 (for cohort studies), the NOS study checklist utilized for this study included eight questions. The mean of the scores assigned independently by four reviewers (MSS, DS, VD, and VS) was used to calculate this meta-analysis's final NOS QA score. Summary statistics were performed on the NOS scores that were obtained. Subgroup analysis was then conducted for studies < or ≥ median NOS score. NOS quality assessment questions and the corresponding assigned scores for each paper are provided in Supplementary Tables 2 and 3. A fifth author (PB) resolved any significant discrepancies throughout the study inclusion, data collection, and the quality assessment process.

2.5. Meta-Analysis

Both breast cancer incidence and mortality data were combined to begin the analysis. Our overall analysis included only mortality for the studies where incidence and mortality were reported. However, each respective metric was incorporated for pertinent cohort analysis. Subgroup analyses were performed based on outcomes (incidence and mortality), study type (cohort, case-control), study region (North America, Europe, Eastern Hemisphere), participants' sex (female, male), industry type (oil industry, chemical industry, miscellaneous (rubber, shoe, and printing industries) and mixed industries), publication year (<2003 and ≥2003), NOS quality score (< median, and ≥ median), and different level of exposure [low, medium, high (Supplementary Table 4)].

Based on the random-effects model, meta-analyses of non-overlapping studies were conducted, and RRs and 95% CIs were estimated [27]. Statistical heterogeneity was calculated by utilizing Cochran's Q test and I2 statistic.

Egger's test and a visual examination of the funnel plot [28] evaluated publication bias. This study's statistical analyses were computed in STATA, version 17.0 BE (Stata Corp., College Station, TX, US).

3. Results

A total of 7,573 studies were obtained from IARC monograph, PubMed, EMBASE, and SCOPUS. In the literature search of recent studies, after a review of the title and abstract, 1,669 publications from the list were excluded while accounting for duplicates. Further, 5,750 manuscripts were excluded upon abstract screening. Out of 154 reports retained with risk estimates for solid cancers, 74 were excluded upon full-text evaluation. Of those 80 studies remaining, 23 were included that reported risk estimates for breast cancer in males and females. The flow chart displaying the selection of the research studies is included in Supplementary Figure 1.

This meta-analysis included 23 studies from various geographical regions: 4 in North America (3 in the United States, 1 in Canada) and 15 in Europe (1 in the United Kingdom, 3 in Italy, 2 in Finland, 1 in Sweden, 1 in Denmark, 2 in Poland, 1 in France, 1 in Russia, 1 in Norway, and 2 mixed), 4 in Eastern Hemisphere Countries (1 in Australia, 2 in China, and 1 in Taiwan). These included 16 studies based on incidence and ten studies based on mortality. The median NOS score was 8 (range: 5.5-10.0). Characteristics of the included studies are reported in Table 1.

Utilizing a random-effects analysis model, the overall RR was 1.17 (95% CI=1.06-1.28, I2=38.6%,p=0.03, n=23 risk estimates, Figure 1). After stratification by the outcome, the summary RR was 1.17 (95% CI=1.05-1.29. I2 =56.1%, p=0.003, n=16, Figure 2) for studies based on incidence and 1.09 (95% CI=0.88-1.37, I2<0.001%, p=0.96, n=10, Figure 3) for studies based on mortality. Exclusion of one study at a time did not provide evidence for results being strongly dependent on a single study (Supplementary Figure. 3).

The results of the stratified analyses are reported in Table 2. Using a random effects model, heterogeneity was demonstrated in the sub-group analysis of

Table 1. Main characteristics of the studies included in the meta-analysis.

First author, year	Country	Study period	Study Design	Type of study	Type of workers	Exposure assement method	Overall Study Sample size	Sex, male, female (%)	Outcome	Variables adjusted for in the analysis other than gender, age and calendar period	NOS score
(Paci et al. 1989) [29]	Italy	1950-84	Cohort	Industry-based	Shoe workers	Documents (plant and inspection records, and information from the glue suppliers)	M 1,008 F 1,005	M 50.1% F 49.9%	Mortality	-	8
(Szeszenia-Dabrowska et al. 1991) [30]	Poland	1945-85	Cohort	Industry-based	Rubber Workers	Job title	M 6978	M 100%	Mortality	-	6
(Lagorio et al. 1994) [31]	Italy	1981-92	Cohort	Industry-based	Service (gas) station attendants	Available employment documents	M 2,308 F 357	M 86.6% F 13.4%	Mortality	-	7
(Satin et al. 1996) [32]	USA	1937-87	Cohort	Industry-based	Oil refinery workers	Job title and available employment documents	M 15,855 F 1,989	M 88.9% F 11.1%	Mortality	-	7
(Collingwood et al. 1996) [33]	USA	1946-87	Cohort	Industry-based	Petroleum refinery	Job title and available employment documents	M 4,433 F 422	M 91.3% F 8.7%	Mortality	-	8
(Lynge et al. 1997) [34]	European Nordic countries: Denmark, Norway, Sweden, Finland	1970-87	Cohort	Community-based	Service station workers	Job title and available employment documents (skin exposure and inhalation)	M 16,524 F 2,445	M 87.1% F 12.9%	Incidence	Smoking status, and alcohol consumption rates considered but not completely adjusted for	7
(Pukkala 1998) [35]	Finland	1971-94	Cohort	Industry-based	Oil refinery	Job title	M 7,512 F 1,942	M 79.4% F 20.6%	Incidence	-	7
(Petralia et al. 1998) [36]	China	1980-84	Cohort	Industry-based	Various jobs with benzene exposure	Job title (questionnaire)	2623	F 100%	Incidence		5.5

(*Continued*)

First author, year	Country	Study period	Study Design	Type of study	Type of workers	Exposure assement method	Overall Study Sample size	Sex, male, female (%)	Outcome	Variables adjusted for in the analysis other than gender, age and calendar period	NOS score
(Bulbulyan et al. 1999) [37]	Russia	1979-93	Cohort	Industry-based	Bookbinders printing industry	Air sampling data	3,473	F 100%	Mortality	-	8
(Petralia et al. 1999) [38]	USA	1986-91	Case control	Hospital-based	Various jobs with benzene exposure	Job exposure matrix	301 cases / 316 controls	F 100%	Incidence		7
(Kauppinen et al. 2003) [39]	Finland	1979-88	Cohort	Industry-based	Chemical laboratory	Job title and employment documents (skin exposure and inhalation)	M 1,037 F 3,673	M 22% F 78%	Incidence	-	8
(Lewis et al. 2003) [40]	Canada	1964-94	Cohort	Industry-based	Petroleum workers	Job title and available employment documents (skin exposure and inhalation)	M 17,230 F 8,062	M 68.1% F 31.9%	Incidence, Mortality	Time since hire	8
(Sorahan et al. 2005) [41]	UK	I: 1971-2001 M: 1968-2002	Cohort	Industry-based	Various jobs with benzene exposure	Job title and available employment documents (skin exposure and inhalation)	M 5,130 F 384	M 93.1% F 6.9%	Incidence, Mortality	-	8
(Costantini et al. 2009) [42]	Italy	1950-2003	Cohort	Industry-based	Shoe factory workers	Industry based job exposure matrix.	F 797	F 100%	Incidence, Mortality	-	7
(Peplonska et al. 2010) [43]	Poland	2000-2003	Case control	Population-based	Various jobs with benzene exposure	Job title (questionnaire)	2,383 cases / 2,502 controls	F 100%	Incidence	Study site, education, body mass index, age at menarche, menopausal status, age at menopause, number of full-term births, age at first full-term birth, breastfeeding, family history of breast cancer and previous screening mammography.	8

(Bonneterre et al. 2012) [44]	France	1979-2002	Cohort	Industry-based	Chlorochemical plant workers	Job title (questionnaire)	M 2,742	M 100%	Incidence	Date of hire	7.5
(Linet et al. 2015) [45]	China	1972-1999	Cohort	Industry-based	Various jobs with benzene exposure	Job title and other details (Available documents and self report)	73,789 benzene-exposed and 34,504 unexposed workers	F 100%	Mortality	-	8
(Glass et al. 2015) [46]	Australia	2009-2011	Case control	Population-based	Various jobs with benzene exposure	Job title (questionnaire)	1,205 cases / 1,789controls	F 100%	Incidence	Exposure to other solvents	8
(Gustavsson et al. 2017) [47]	Sweden	1950-89	Cohort	Industry-based	Chemical laboratory workers	Job title and other details (documents and self report)	F 2,245	F 100%	Incidence	-	8
(Laouali et al. 2018) [48]	European countries (Denmark, France, Germany, Italy, Latvia, Portugal, Spain, and Sweden)	1995-97	Case control	Population-based	Various jobs with benzene exposure	Job title (questionnaire)	104 cases / 1,901 controls	M 100%	Incidence	Country, education, body mass index, alcohol consumption, all solvents	8.5
(Pedersen et al. 2020) [49]	Denmark	1964-2016	Case control	Population-based	Various jobs with benzene exposure (1-9y)	Job title (questionnaire)	F 38,375	F 100%	Incidence	Parity, age at first live birth, heavy physical activity at work, reproductive factors, socioeconomic status	8
(Liu et al. 2022) [50]	Norway	1965-98	Cohort	Industry-based	Petroleum workers	Job title and other details (documents and self report)	F 600 (86 cases and 514 non-cases)	F 100%	Incidence	Education	10
(Westra S et al., 2023) [51]	Canada	2008-11	Case control	Population-based	Various jobs with benzene exposure	Job title (questionnaire)	1246 (661 case and 587 cntrol)	F 100%	Incidence	-	5.5

HR: hazard ratio, SMR: standardized mortality ratio, SIR: standardized incidence ratio, RR: relative risk, ICD: International Classification of Diseases. Standardized: as per standard SMR calculation, all studies were adjusted for age, calendar period, and sex.

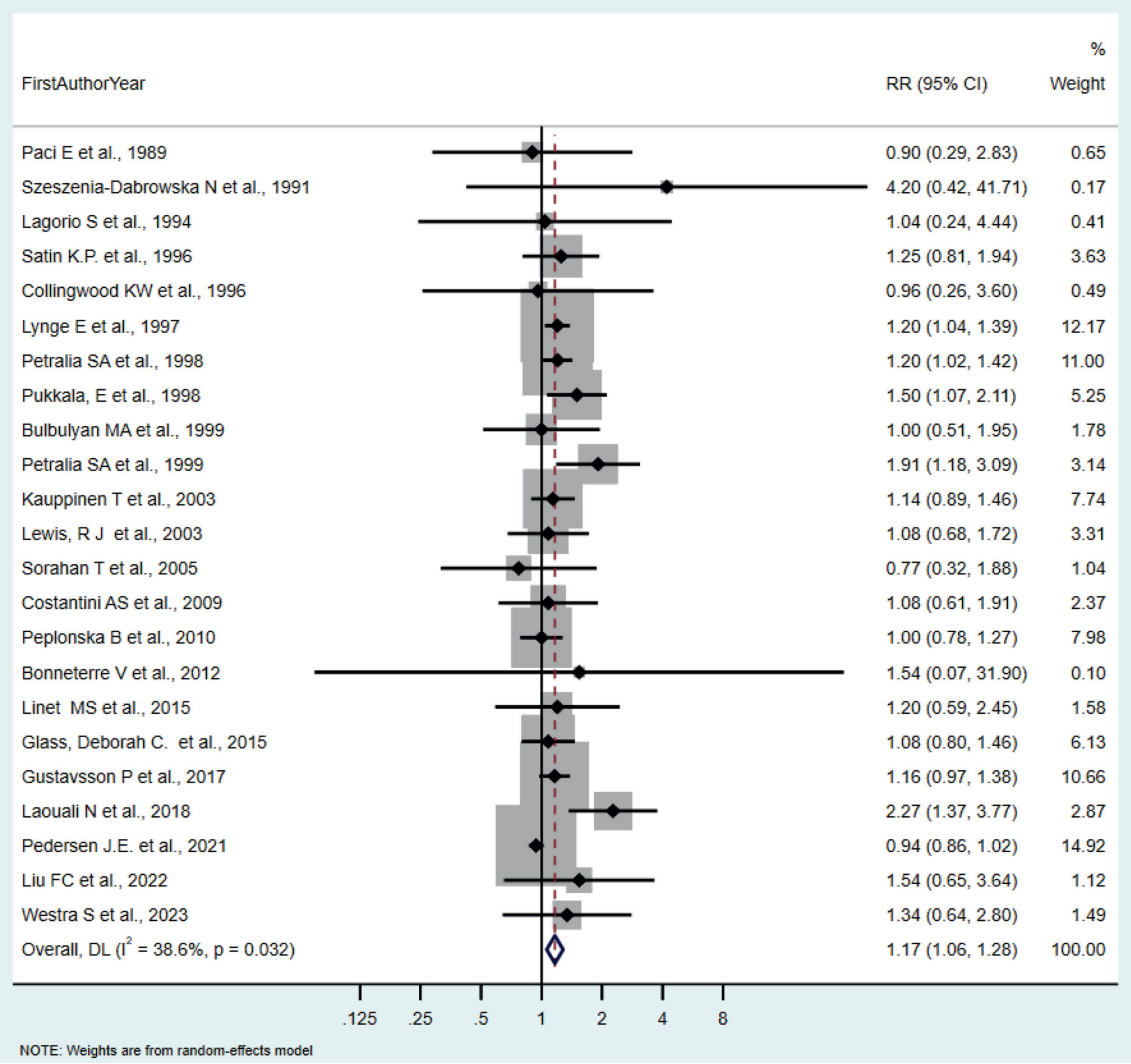

Figure 1. Forest plot with results of the overall meta-analysis of studis on occupational exposure to benzene and breast cancer.

studies. Based on sub-analyses by sex, heterogeneity was detected between sexes (p-het=0.004), and female subjects were observed to have a summary RR of 1.13 (95% CI=1.04-1.22, I2=23.8%,p=0.16, n=21) driven by incidence with an RR of 1.13 (95% CI=1.03-1.24, I2=45.7%, p= 0.03, n=12). Summary RR for males was reported to be 2.33 (95% CI=1.42-3.83, I2<0.001%,p=61, n=2).

No heterogeneity was detected in the subgroup analysis based on quality score (p-het=0.06), years of publication (p-het=0.10), study design (p-het=0.78), geographical region (p-het=0.10), industry of employment type (p-het=0.86), and level of exposure (low, high; p-het=0.87), although the RR for high level of exposure showed positive association with breast cancer 1.35 (95% CI=1.06-1.72, I2 =<0.001%,p=0.65, n=3).

Egger's test was performed to detect publication bias in the included studies; evidence of such bias was found (p=0.03). In addition, qualitatively, asymmetry in the contour-enhanced funnel plot was evident (Supplementary Figure 2).

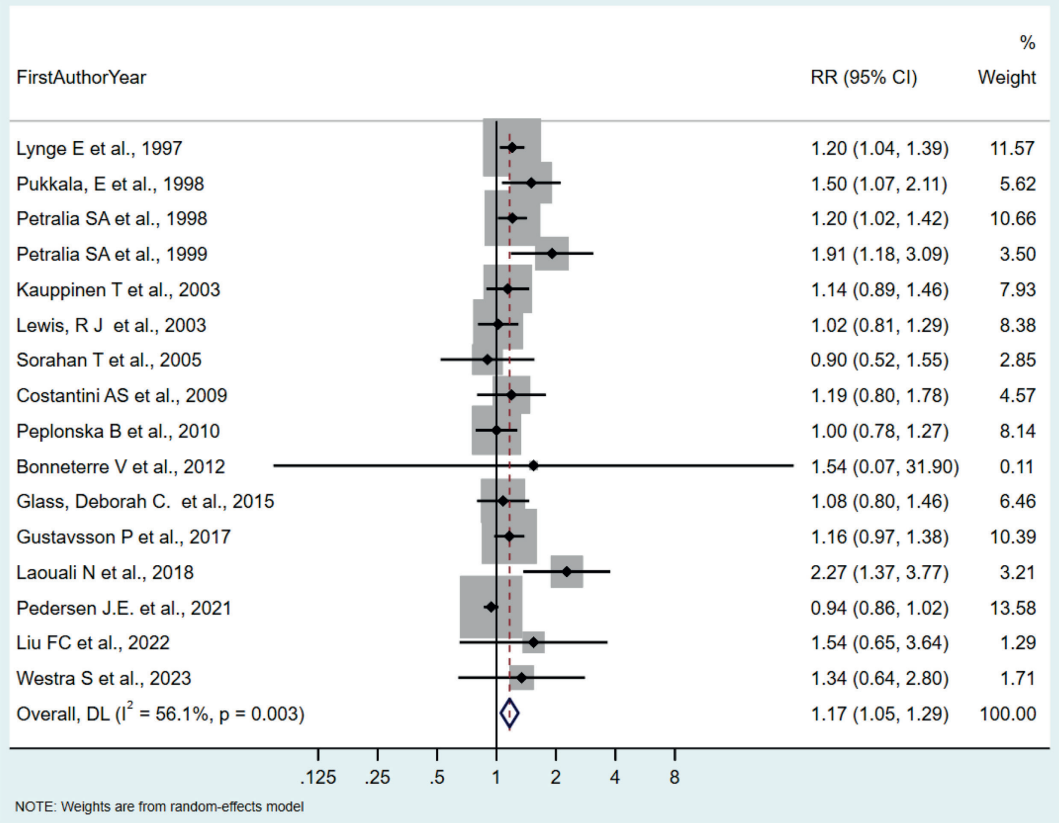

Figure 2. Forest plot with results of the overall meta-analysis of studies on occupational exposure to benzene and incidence of breast cancer.

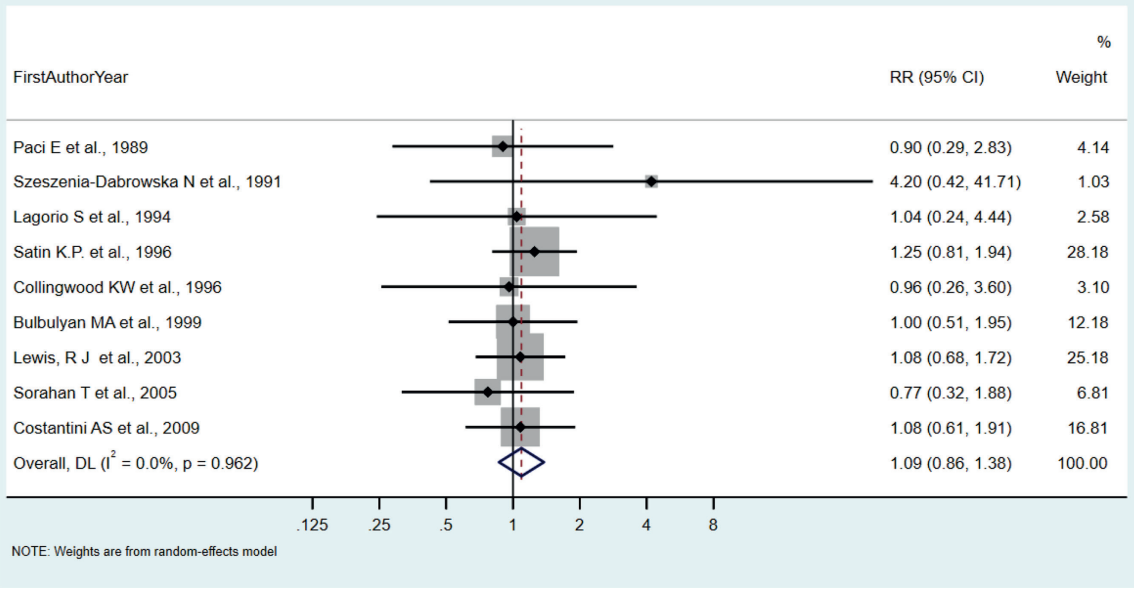

Figure 3. Forest plot with results of the overall meta-analysis of studies on occupational exposure to benzene and mortality of breast cancer.

Table 2. Results of the meta-analysis on the association between occupational exposure to benzene and breast cancer.

Outcome	Stratum	n of risk estimates	RR	95% CI	I^2 (95%CI), p-value	p-het
Incidence and mortality (Overall)	**Overall**	23	1.17	1.06-1.28	38.6% (0.0%-66.4%), 0.03	-
	Sex					0.004
	Female	21	1.13	1.04-1.22	23.8% (0.0%-56.9), 0.16	
	Male	2	2.33	1.42-3.83	<0.001% (0.0%-24.5 %), 0.61	
	Publication year					0.10
	Prior to 2003	10	1.24	1.13-1.37	<0.001% (0.0%-52.7), 0.68	
	2003 or after	13	1.10	0.98-1.23	34.2% (0.0%-64.8) , 0.11	
	Region					0.56
	North America	5	1.34	1.05-1.71	<0.001% (0.0%-64.1%), 0.51	
	Europe	15	1.15	1.02-1.31	52.5% (0.0%-72.7%), 0.01	
	Eastern Hemisphere Countries	4	1.17	1.01-1.34	<0.001% (0.0%-67.9), 0.89	
	Industry Type					0.86
	Petroleum Industry	7	1.23	1.09-1.39	<0.001% (0.0%-40.9%), 0.90	
	Chemical Industry	3	1.15	1.00-1.33	<0.001%(0.0%-0.0%) , 0.98	
	Miscellaneous (shoe, rubber, printing industries.)	4	1.07	0.72-1.60	<0.001% (0.0%-47.0%), 0.68	
	Mixed Industries	9	1.18	0.99-1.41	67.5% (0.0%-88.1%), 0.002	
	Quality score					0.06
	< median	10	1.25	1.13-1.38	<0.001%(0.0%-39.0), 0.74	
	≥ median	13	1.08	0.97-1.21	31.9% (0.0%-67.2), 0.13	
	level of exposure (Dose category)					0.87
	Low	3	1.27	0.66-2.45	72.3% (0.0%-92.7%), 0.03	
	High	3	1.35	1.06-1.72	<0.001% (0.0%-44.7 %), 0.65	
	Study Type					0.78
	Case-control	6	1.24	0.96-1.58	74.8% (0.0%-91.9), <0.001	
	Cohort	17	1.19	1.10-1.29	<0.001% (0.0%-26.9%), 0.99	
Incidence	**Overall**	16	1.17	1.05-1.29	56.1% (0.0%-78.7%), 0.003	-
	Sex					0.008
	Female	15	1.13	1.03-1.24	45.7% (0.0%-73.1%), 0.03	
	Male	1	2.27	1.37-3.77	<0.001% (N/A) , N/A	
	Publication year					0.07
	Prior to 2003	4	1.29	1.12-1.48	34.8% (0.0%-79.7%), 0.20	
	Post-2003	12	1.09	0.98-1.22	40% (0.0%-72.0), 0.07	
	Region					0.84
	North America	3	1.32	0.86-2.04	63.3% (0.0%-90.5%), 0.07	
	Europe	11	1.16	1.02-1.32	61.7% (0.0%-84.0%), 0.004	
	Eastern Hemisphere Countries	2	1.17	1.01-1.36	<0.001% (0.0%-46.4%), 0.54	
	NOS score					0.08
	< median	6	1.25	1.13-1.39	<0.001% (0.0%-58.4%), 0.46	

Outcome	Stratum	n of risk estimates	RR	95% CI	I^2 (95%CI), p-value	p-het
	≥ median	10	1.08	0.96-1.23	53.2% (0.0%-80.7%), 0.03	
Mortality	**Overall**	10	1.09	0.86-1.38	<0.001% (0.0%-18.0), 0.96	-
	Sex					0.25
	Female	9	1.08	0.85-1.36	<0.001% (0.0%-15.3%), 0.99	
	Male	1	4.20	0.42-41.71	<0.001% (N/A), N/A	
	Publication year					0.64
	Prior to 2003	6	1.15	0.83-1.60	<0.001% (0.0%-37.6%), 0.88	
	2003 or after	4	1.03	0.74-1.44	<0.001% (0.0%-26.4%), 0.89	
	Region					0.86
	North America	3	1.15	0.85-1.57	<0.001% (0.0%-37.1%) , 0.87	
	Europe	5	1.02	0.67-1.55	<0.001% (0.0%-38.0%), 0.75	
	Eastern Hemisphere Countries	2	1.00	0.51-1.95	<0.001% (N/A), NA	
	NOS score					0.41
	< median	4	1.21	0.86-1.69	<0.001% (0.0%-52.2%), 0.72	
	≥ median	6	0.99	0.72-1.37	<0.001% (0.0%-17.3%), 0.98	

RR: relative risk, CI: confidence interval, nc: not computable, na: not applicable.

4. Discussion

To our knowledge, this is the first meta-analysis investigating the association between occupational exposure to benzene and breast cancer, providing for an improved characterization of this agent's carcinogenicity. An association between occupational exposure to benzene and breast cancer was elucidated overall, predominantly driven by incidence and particularly when exposed to higher levels of benzene.

Regarding pathogenesis, benzene is detoxified in the liver via the CYP2E1 cytochrome P450 system, producing harmful benzene-oxide metabolites. Toxic effects of benzene oxide-oxepin have been confirmed in vivo, whereby this metabolite blocks one-electron oxidation by cytochrome P450 monooxygenase, resulting in the (E, Z)-muconaldehyde. Benzene-oxide may induce significant genotoxicity and thus yield malignancy [15, 18]. Additionally, the lung may metabolize benzene, whereby the CYP2F1 and CYP2A13 enzymes produce the toxic benzene-oxide metabolites. *In vivo*, benzene-oxide is in equilibrium with its tautomer, oxepin, which may spontaneously form phenol, and excess metabolite may be hydrolyzed to produce catechol and 1,2-benzoquinone. These metabolites are then further catalyzed to produce S-phenylmercapturic acid. Benzene and its metabolic byproducts have demonstrated the potential to induce hematotoxicity, chromosomal aberrations, and selective chromosomal aneuploidy. Such genotoxic alterations may present with variations in microRNA expression [52].

These toxic metabolites may have teratogenic effects, as evidenced by maternal benzene exposure with subsequent alterations in the developmental and functional properties of hematopoietic stem cells in fetuses and children [53]. Of relevance, *in vivo*, experimentation has demonstrated a correlation between benzene exposure and breast cancer risk, specifically frequent p53 and H-ras mutations inducing mammary gland carcinomas [54-57]. In addition to the genotoxic effects, benzene and its toxic byproducts may exhibit endocrine-disrupting properties [58-60]. For example, such compounds may bind to the estrogen receptors of the breast, interfere with the normal function of estrogen-mediated pathways, and alter gene expression [61]. As a result, the

mammary gland is at risk of dysplasia and neoplastic transformation [62, 63].

Studies published before 2003 demonstrated an association, while those published in the year 2003 or after did not. This may be validated by a 1997 alignment of North American and European regulatory standards, which limit benzene exposure to 1.63-3.25 mg/m3 (0.5-1 ppm) [64]. One may speculate that this finding is due to improved occupational benzene safety over time; however, this finding requires further inquiry. Despite not discovering any noteworthy disparity between low and high levels of exposure, it is worth noting that a higher level of exposure exhibited a stronger correlation. Furthermore, these findings were particularly pronounced in workplaces related to petroleum and chemistry.

The evaluation of sub-groups based on study design showed varied results. A correlation was observed in cohort studies, possibly due to the higher number of cohort studies (n=17) compared to case-control studies (n=6) in this analysis. However, it is crucial to acknowledge that cohort studies may lack adjustments in their modeling to account for confounding variables, including cigarette smoke, secondhand tobacco smoke, alcohol consumption, genetic mutations such as BRCA, family history, and exposure to other environmental toxins [65-69].

Our study has several strengths. First, this is the only systematic review and meta-analysis regarding the risk of breast cancer in workers with occupational exposure to benzene. To ensure a comprehensive analysis, we extensively screened and reviewed the literature, including all relevant recent studies. Data analysis was performed with a validated methodology for meta-analysis. Five authors (MSS, MB, DS, VD, and VS) independently verified all aspects of data extraction and quality assessment, thereby optimizing accuracy and comprehensiveness of the overall analysis. Additionally, this association was depicted from various perspectives by computing several stratified calculations. Overall heterogeneity was tested and was observed to be I2<50% for all the studies.

Our study has limitations. We found evidence of publication bias, which could be interpreted because of some variation in the study design of different studies and included subjects' features, for example, hormone-related breast cancer or menopause situation and so on. Only 8 of the 23 studies evaluated adjusted for at least one confounding variable other than age and period calendar, and therefore, insufficiently accounted for possible confounding effects or bias. Due to limited control over confounding variables, we were unable to address the impact of individual participants' characteristics in each study, such as reproductive histories compared to referent populations (e.g., individuals with children being more likely to leave the workforce) or low socioeconomic status. These factors may have led to over- or under-estimate of the results. Also, we couldn't fully evaluate the impact of different durations of benzene exposure and time since cessation of exposure due to limited studies and risk estimates. Furthermore, with studies that collected exposure through questionnaires or self-reports, there could be a possibility of interview or memory bias, which may lead to differential misclassification. In addition, our results cannot be generalized to male breast cancer cases as there was an insufficient sample size of male breast cancer studies to run any meaningful statistics or draw remarkable conclusions.

5. Conclusion

In conclusion, our meta-analysis has found a correlation between occupational benzene exposure and the incidence of breast cancer, although bias and confounding prevent any conclusion in terms of causality. Nonetheless, it is recommended that workers take necessary safety precautions to avoid the potential adverse health consequences associated with such exposure. To fully understand the relationship between occupational benzene exposure and the risk of breast cancer, future studies should be well-designed. They should consider factors such as varying duration of exposure, clinical and hormonal characteristics of breast tumors, and other important confounders. These studies will help in complying with the newer occupational benzene exposure regulations.

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Supplementary Materials:
Supplementary Table 1: Detailed search strategy used on the different databases.
Supplementary Figure 1. Flow diagram of the study selection process.
Supplementary Figure 2. Contour-enhanced funnel plot to study publication bias in breast cancer studies with incidence and mortality combined.
Supplementary Figure 3: Leave-one-out meta-analysis for the association between occupational benzene exposure and breast cancer incidence and mortality combined.
Supplementary Table 2. Modified version of the Newcastle-Ottawa Scale (NOS) for case-control studies adopted for quality assessment.
Supplementary Table 3. Modified version of the Newcastle-Ottawa Scale (NOS) for cohort studies adopted for quality assessment.
Supplementary Table 4. Details of results on level-response relationship

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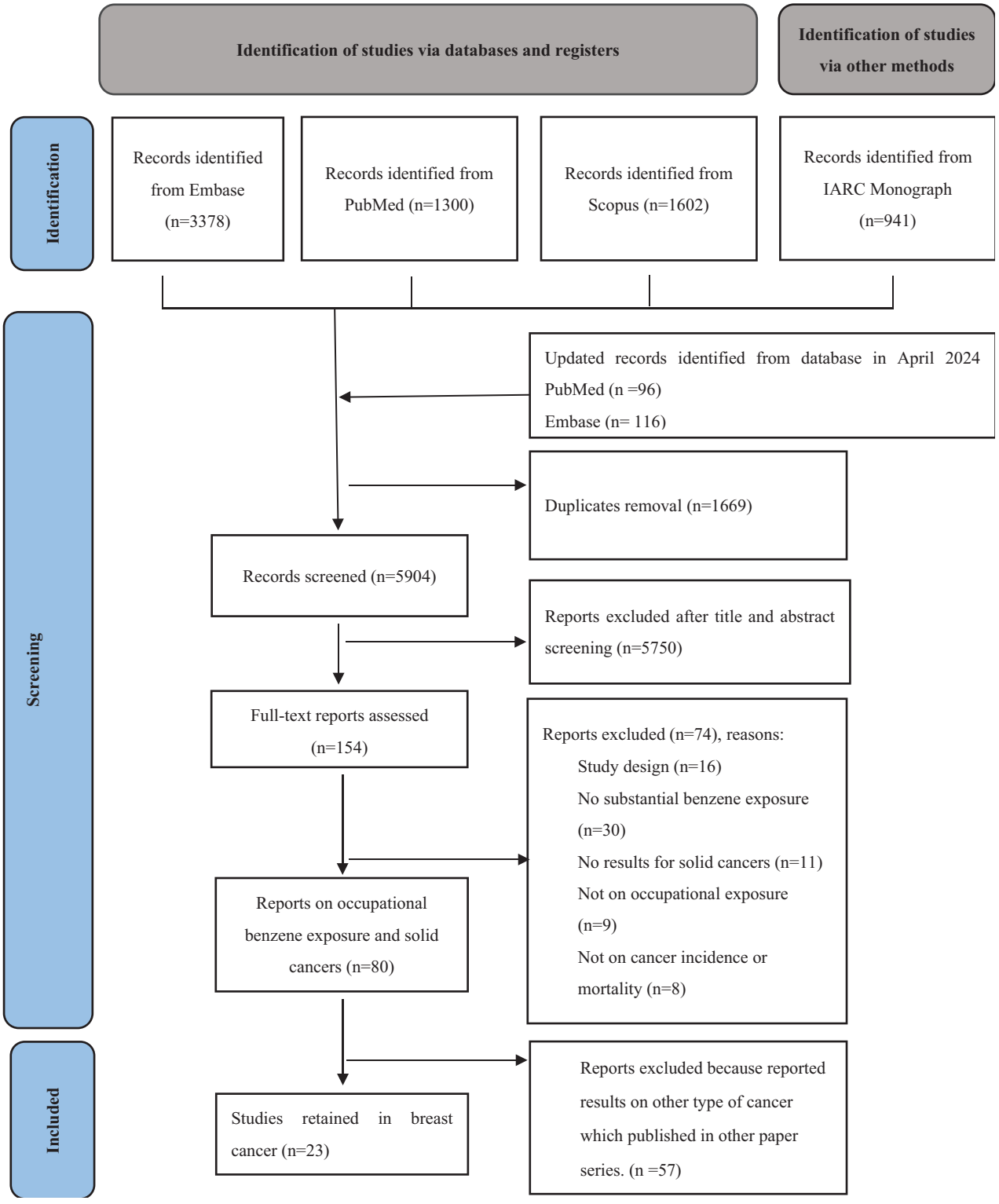
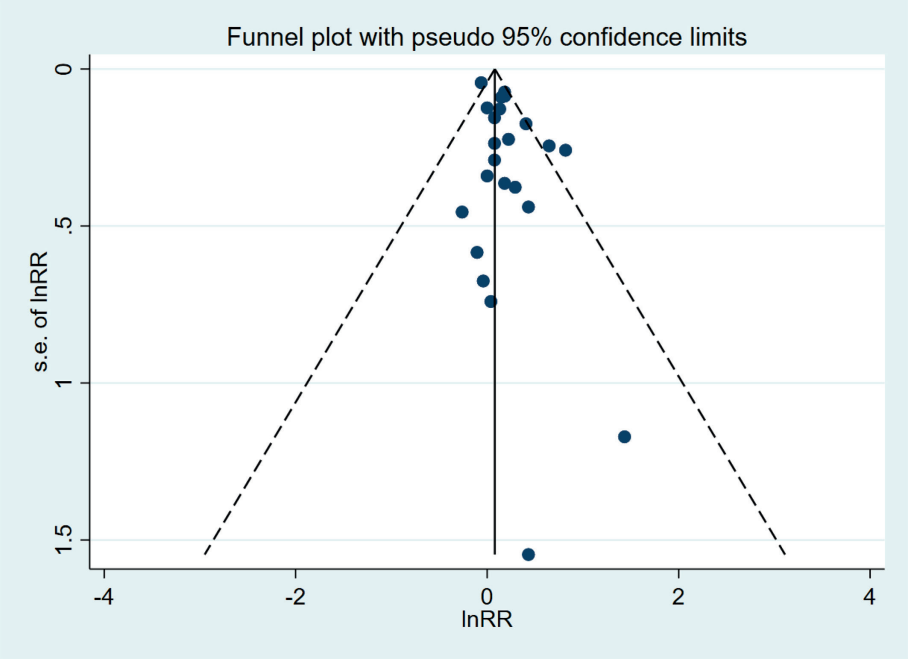
Supplementary Material

Supplementary Table 1. Detailed search strategy used on the different databases.

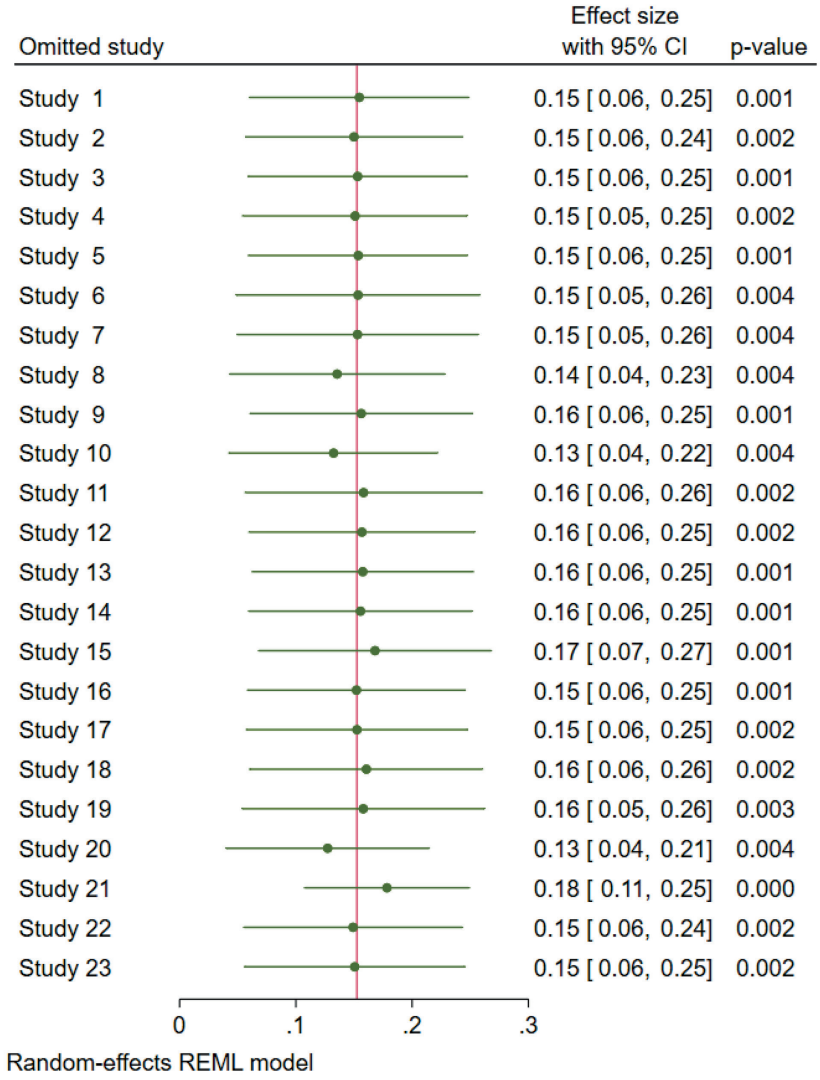
Database	Search string
PubMed	(("neoplasms"[Title/Abstract] OR "carcinoma"[Title/Abstract] OR "cancer"[Title/Abstract] OR "malignant"[Title/Abstract]) AND ("benzene"[Title/Abstract] OR "benzol"[Title/Abstract] OR ("cyclohexa-1"[All Fields] AND "3 5 triene"[Title/Abstract]) OR (("1"[All Fields] AND "3"[All Fields]) AND "5-cyclohexatriene"[Title/Abstract]) OR "cyclohexatriene"[Title/Abstract])) AND ((humans[Filter]) AND (english[Filter] OR french[Filter] OR german[Filter] OR italian[Filter] OR spanish[Filter]))
Embase (Ovid)	("benzene" or "benzol" or "cyclohexa-1,3,5-triene" or "1,3,5-cyclohexatriene" or "cyclohexatriene").tw. and ("neoplasms" or "carcinoma" or "cancer" or "malignant").tw. limit to ((behavioral & social sciences or clinical medicine or health professions or life sciences or medical humanities or nursing or patient education or public health or science) and original articles)
Scopus	((TITLE-ABS-KEY (benzene) OR TITLE-ABS-KEY (benzol) OR TITLE-ABS-KEY (cyclohexa-1,3,5-triene) OR TITLE-ABS-KEY (1,3,5-cyclohexatriene) OR TITLE-ABS-KEY (cyclohexatriene))) AND ((TITLE-ABS-KEY (neoplasms) OR TITLE-ABS-KEY (carcinoma) OR TITLE-ABS-KEY (cancer) OR TITLE-ABS-KEY (malignant))) AND (LIMIT-TO (DOCTYPE , "ar") OR LIMIT-TO (DOCTYPE , "re")) AND (LIMIT-TO (SUBJAREA , "MEDI") OR LIMIT-TO (SUBJAREA , "ENVI")) AND (LIMIT-TO (LANGUAGE , "English") OR LIMIT-TO (LANGUAGE , "German") OR LIMIT-TO (LANGUAGE , "Italian") OR LIMIT-TO (LANGUAGE , "French") OR LIMIT-TO (LANGUAGE , "Spanish")) AND (LIMIT-TO (SRCTYPE , "j")) AND (EXCLUDE (SUBJAREA , "BIOC") OR EXCLUDE (SUBJAREA , "EART") OR EXCLUDE (SUBJAREA , "ENGI") OR EXCLUDE (SUBJAREA , "CENG")) AND (EXCLUDE (SUBJAREA , "COMP") OR EXCLUDE (SUBJAREA , "MATH")) AND (EXCLUDE (LANGUAGE , "Portuguese") OR EXCLUDE (LANGUAGE , "Turkish"))



Supplementary Figure 1. Flow diagram representing selection of studies for inclusion in the review and meta-analysis.



Supplementary Figure 2. Contour-enhanced funnel plot to study publication bias in breast cancer studies with incidence and mortality combined.



Supplementary Figure 3. Leave-one-out meta-analysis for the association between occupational benzene exposure and breast cancer incidence and mortality combined.

Supplementary Table 2.

NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE
CASE CONTROL STUDIES (maximum score: 9)
Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

1. **Is the case definition adequate?**
   a. yes, with independent validation **(1)**
   b. yes, eg record linkage **(1)** or based on self-reports **(0.5)**
   c. no description **(0)**
2. **Representativeness of the cases**
   a. consecutive or obviously representative series of cases **(1)**
   b. potential for selection biases or not stated **(0)**
3. **Selection of Controls**
   a. community controls **(1)**
   b. hospital controls **(0.5)**
   c. no description **(0)**
4. **Definition of Controls**
   a. no history of disease (endpoint) **(1)**
   b. no description of source **(0)**

Comparability

1. **Comparability of cases and controls on the basis of the design or analysis**
   a. study controls for age, gender, province **(0)**
   b. study controls for age, gender, province +smoking **(1)**
   c. study controls for age, gender, province +smoking + other additional factors **(2)**

Exposure

1. **Ascertainment of exposure**
   a. secure record (eg surgical records) **(1)**
   b. structured interview where blind to case/control status **(1)**
   c. interview not blinded to case/control status **(0.5)**
   d. written self-report or medical record only **(0.5)**
   e. no description **(0)**
2. **Same method of ascertainment for cases and controls**
   a. yes **(1)**
   b. no **(0)**
3. **Non-Response rate**
   a. one or both groups over 90% **(1)**
   b. one or both groups between 60- 90% **(0.5)**
   c. one or both groups under 60% **(0)**
   d. no statement **(0)**

Supplementary Table 3.

NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE
COHORT STUDIES (maximum score: 10)
Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

Selection

1. **Representativeness of the exposed cohort**
   a. truly representative of the average _____ (describe) in the community **(2)**
   b. somewhat representative of the average _____ in the community **(1)**
   c. selected group of users eg nurses, volunteers **(0.5)**
   d. no description of the derivation of the cohort **(0)**
2. **Selection of the non-exposed cohort**
   a. drawn from the same community as the exposed cohort **(1)**
   b. drawn from a different source **(0.5)**
   c. no description of the derivation of the non-exposed cohort **(0)**
3. **Ascertainment of exposure**
   a. secure record (eg surgical records) **(1)**
   b. structured interview **(1)**
   c. written self-report **(0.5)**
   d. no description **(0)**
4. **Demonstration that the outcome of interest was not present at the start of the study**
   a. yes **(1)**
   b. no **(0)**

Comparability

1. **Comparability of cohorts based on the design or analysis**
   a. study controls for age, gender, province **(0)**
   b. study controls for age, gender, province +smoking **(1)**
   c. study controls for age, gender, province +smoking + other additional factors **(2)**

Outcome

1. **Assessment of outcome**
   a. independent blind assessment **(1)**
   b. record linkage **(1)**
   c. self-report **(0.5)**
   d. no description **(0)**
2. **Was follow-up long enough for outcomes to occur**
   a. yes (select an adequate follow-up period for the outcome of interest) **(1) (average 15 years)**
   b. no **(0)**
3. **Adequacy of follow-up of cohorts**
   a. complete follow-up - all subjects accounted for over 90% **(1)**
   b. subjects lost to follow-up unlikely to introduce bias - small number lost - > ____ % (select an
   c. adequate %) follow up, or description provided of those lost) between 60- 90% **(0.5)**
   d. follow-up rate < ____% (select an adequate %) and no description of those lost under 60% **(0)**
   e. no statement **(0)**

Supplementary Table 4. Details of results on level-response relationship

first author name	Dose details	Dose category	Outcome	RR (95%CI)
Petralia SA,1998	N/A	High	incidence	1.3 (1-1.7)
	N/A	Low		0.9 (0.6-1.3)
Costantini AS, 2009	>40ppm-y	High	mortality	1.31 (0.54-3.14)
	<=40 ppm-y	Low		0.96 (0.45-2.01)
Laouali N, 2018	>=0.87ppm_y	High	incidence	1.9 (0.9-4.1)
	>0<0.87 ppm_y	Low		2.6 (1.3-5.1)

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Depression and Anxiety in Voluntarily Unemployed People: A Systematic Review

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Keywords: Voluntarily Unemployed; Inactive Workers; Mental Health Outcomes

Abstract

Background: *Unemployment impacts people's physical and psychological well-being, and gender and age affect mental health among the unemployed. Despite the correlation between unemployment and negative mental health outcomes being largely investigated in scientific literature, research on voluntarily unemployed individuals is scarce. A systematic review was performed on studies evaluating mental health outcomes in voluntarily unemployed adults.* **Methods:** *Following the PRISMA statements, three databases were screened; research articles written in English investigating the relationship between mental health outcomes and employment status were included. The quality of articles was assessed using the Newcastle-Ottawa Scale.* **Results:** *The initial search yielded 727 records; 4 studies were included in this systematic review. One study reported voluntarily unemployed people as less depressed than employed and unemployed people, one as more depressed than employed but less than unemployed people, one reported voluntarily unemployed people as less anxious but more depressed than employed and less anxious and depressed than unemployed people, one study reported voluntarily unemployed men as depressed and anxious more often than employed men. Further research should investigate mental health outcomes in voluntarily unemployed people and strategies to bring back these individuals into the workforce.*

1. Introduction

The impact of unemployment on people's health is a pressing issue that deserves attention. In particular, understanding how age and gender affect mental health issues among unemployed people is crucial to develop effective support systems and interventions.

Numerous studies have explored the relationship between unemployment and health outcomes, particularly mental health. A meta-analysis conducted by Milner et al found that unemployment was significantly associated with a higher risk of suicide, even after adjusting for prior mental health conditions [1]. Moreover, unemployment is associated with increased rates of depression, anxiety, and other mental health disorders [2].

Unemployment can profoundly affect mental well-being, and this impact can vary across different

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age groups [3]. Younger individuals who are unemployed may experience feelings of anxiety, stress, and uncertainty about their future prospects. The lack of financial stability and the pressure to establish a career can take a toll on their mental health. Unemployment is a significant social and economic issue with far-reaching consequences, including its impact on people's health [3]. Norström et al., 2014 performed a systematic review focusing on effects in age subgroups. They found that age was one of the factors influencing the relationship between unemployment and self-assessed health [4].

Older individuals may face additional challenges in finding employment, which can contribute to poorer health outcomes, considering the impact that age has on mental health [5]. Unemployment among older people has been associated with depressive symptoms [6] and late-life depression [7]. Furthermore, older adults tend to be less skilled in technology use [8], which could have further distanced unemployed older individuals from the occupational world during the COVID-19 pandemic due to the shift towards remote working, which has in and itself impacted mental and physical health of workers [9].

Gender differences also seemingly play a role in the relationship between mental health and unemployment, with men being more affected by unemployment than women [10, 11], in contrast to the working population, where women are more affected by mental health problems than men [12].

Other factors have been reported to influence negatively the mental health of unemployed people, such as the presence of family responsibilities, which affected men especially, causing poorer mental health outcomes [10]. Furthermore, social class may mediate the relationship between unemployment and mental health [10].

As highlighted by the European Psychiatric Association guidelines, poor mental health is not the only outcome associated with unemployment, especially within economic crises: alcohol abuse, somatoform disorders, as well as mood and anxiety disorders have been associated with economic crises [13].

In the context of unemployment and mental health, mentioning a possible "reverse causality" effect is paramount. It has been reported that jobs with a negative effect on the mental health of workers lead to higher turnover, which means that in some cases, poor mental health could be the cause of unemployment rather than the contrary [14, 15]. However, studies performed using the fixed-effect model indicate that unemployment negatively affects mental health with a causal process [16,17]. A longitudinal study by Fergusson et al. reported that exposure to unemployment accounted for a median of 10.8% of the risk of negative mental health outcomes [17].

A different category of non-working people than unemployed are NEETs. The acronym NEET stands for "Not in Education, Employment, or Training" and indicates the disengagement of young people from entering adult life, the labour market, and the possibility of accessing it through education or training [18]. This class represents a particular subcategory of people who are unemployed both for voluntary and involuntary reasons. Gariépy et al. Highlighted that the NEET population could face a higher rate of anxiety, behaviour problems, alcohol use and psychological distress compared to the general population, as well as a higher rate of cannabis use, drug use and suicidal ideation [19].

Despite the correlation between unemployment and negative mental health outcomes being largely investigated in scientific literature, as already described, research on voluntarily unemployed, also known as inactive individuals, is scarce. Voluntarily unemployed people voluntarily leave their employment and do not seek another job. Therefore, voluntary unemployment is not due to the unavailability of a job but due to a decision made by the person leading them to not seek employment. In 2018, 39% of the world's working-age population was outside the labour force (25% of the male and 52% of the female working-age population), and the most represented age demographics were over 64 years (around 80%) and under 24 years (around) of age [20].

Recognizing voluntarily unemployed people is difficult, as they are often discouraged workers who tend to be either young and feeling disconnected from the job market or at the end of their occupational life and would rather distance themselves from working until retirement rather than start anew. However, it has been reported that 6% of the

people outside the labour force are potential workers, and this percentage is even higher in younger people; furthermore, over half of the people outside the labour force are available for work, although not actively seeking employment [20], identifying voluntarily unemployed people as "discouraged workers".

The aim of this systematic review is to investigate mental health outcomes (depression and anxiety) in voluntarily unemployed people compared to unemployed or employed people.

This systematic review focuses on voluntarily unemployed people to assess what is already known about the psychological wellbeing of this population. Being outside the workforce implies less opportunity to reach this population, with difficulty assessing their psychological well-being. This review is motivated by the need to assess the impact of unemployment is a decision made by the person themselves rather than imposed upon them by external factors, comparing their mental health outcomes with unemployed and employed people.

Furthermore, this review aims to assess the need to implement policies and interventions to ensure the mental well-being of voluntarily unemployed people by investigating if worse mental health outcomes are present in this marginalized population.

2. Methods

This systematic review was performed adhering to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statements [21].

Three databases were searched: PubMed, ISI Web of Knowledge, and Scopus. A query was developed following the PECO model, establishing the Population (P) as voluntary unemployed people, the Exposure (E) as unemployment, Comparison (C) as employed and involuntarily unemployed people, and the Outcome (O) as anxiety or depression.

The query used to perform the bibliographic search was: ("voluntarily unemployed" OR unemploy* OR jobless OR unoccupied OR inactive OR "discouraged work*") AND (anxiety OR depression). Results were filtered by language (English language only) and time period (records published within the last 10 years only).

The research was restricted to articles investigating anxiety and depression traits in voluntarily unemployed people and published up until May 2023, when the initial search was performed. Two researchers screened the records using blind methodology, and at the end of the screening process, all conflicts were resolved by discussing the studies with a third researcher. Studies were excluded from the review if they did not use validated questionnaires to measure anxiety or depression. Non-research articles (commentaries, letters, and editorials) were excluded from the systematic review. The initial screening by title and abstract was performed through the website Rayyan [22]. A study was selected for a more detailed review if it fulfilled the following criteria: (i) One of the aims of the study was to investigate mental health, particularly depression or anxiety; (ii) the manuscript was published in English; (iii) it was a full-text article; (iv) the subject studied was voluntarily unemployed people [23].

A quality assessment was performed for the included studies using the Newcastle-Ottawa Scale (NOS) [24], and the following aspects were considered: selection score (representativeness of the sample, sample size, non-respondents, ascertainment of risk factor), comparability score, outcome score (assessment of outcome, statistical analysis performed). The score is 0-5 for selection, 0-2 for comparability, 0-3 for outcome, 0-10 overall. Studies with a score of 8 or higher were considered of good methodological quality, studies with 5-7 were considered of fair methodological quality, and studies under 4 points were considered of poor methodological quality.

The studies were considered heterogeneous regarding the population studied, outcome measures, time period, and confounding factors. To perform a meta-analysis, it was impossible to pool the data statistically, so we performed a "best evidence" synthesis instead [25, 26]. The studies were classified according to the type of study design. The prospective cohort study was judged as the preferred design, followed by the case-control study and then by the cross-sectional study. The studies were then ranked by their methodological quality score. The overall evaluation of the degree of evidence of a causal relationship between mental health outcomes and

voluntarily unemployed people was then reported considering the following levels of evidence [26].

- Strong evidence: consistent results in ≥2 strong/moderate quality studies.
- Moderate evidence: consistent results in one strong/moderate quality study and at least one weak-quality study or consistent results in ≥2 weak-quality studies.
- Insufficient evidence: only one available study or inconsistent results in ≥2 studies.

This study was conducted as part of the research (Im)perfetti sconosciuti. "(Im)perfect strangers: a trans-disciplinary study on the phenomenon of inactivity among adult men," is funded by the Catholic University of the Sacred Heart through the Line of Intervention of University Interest Research (year 2022).

3. Results

The initial search resulted in 727 records; after removing 368 duplicates, 359 articles were screened by title and abstract. After the initial exclusion, 76 records were assessed by full text, and 4 studies were included in this systematic review. Studies were selected if voluntarily unemployed people were included in the sample**,** and the mental health outcomes investigated in the study were assessed for this population as a separate sub-group.

The PRISMA flowchart with the detailed inclusion process is reported in Figure 1.

The included studies were assessed using the NOS. Three of the studies report evidence of an association of mental health with occupational status and good methodological quality (8 points on the NOS scale) [27-29]; the fourth study is strongly suggestive of an association of mental health with

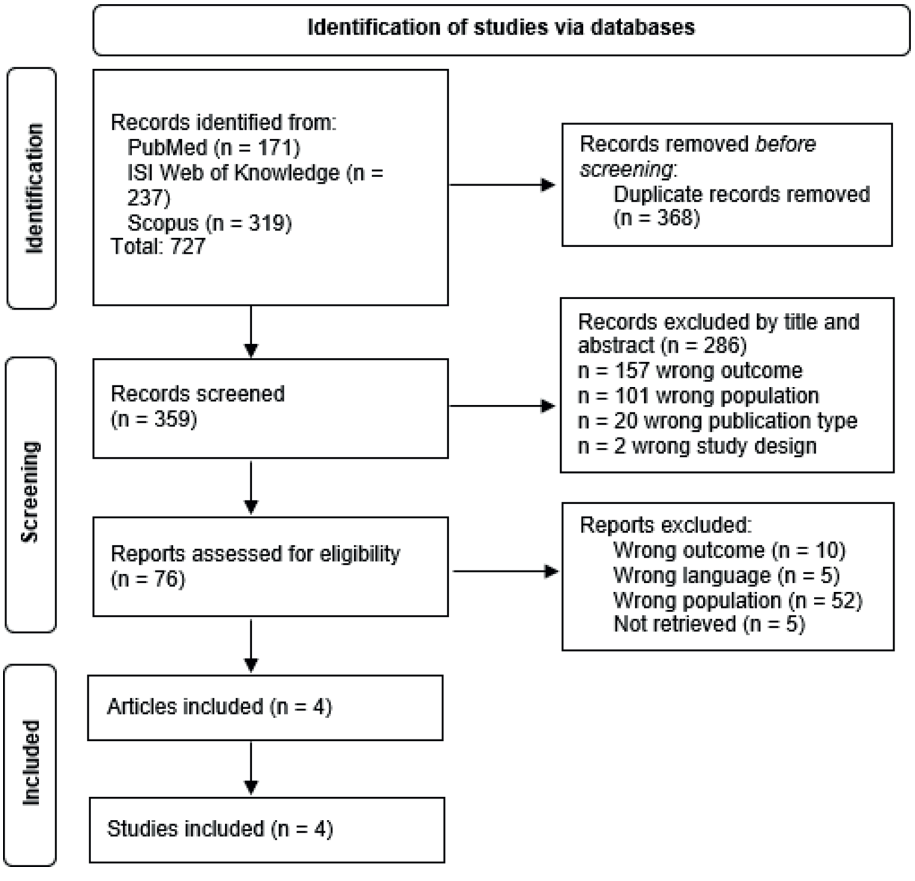

Figure 1. PRISMA Flowchart.

Table 1. Data extraction from included studies.

Authors	Country	Study timeframe	Sample size	Mental health outcomes	Correlation between mental health outcomes and employment status			
					Analysis	Correlation		p-value
Buffel et al. (2015)	20 EU countries	2006 and 2012	51679	Depression (CES-D)	Regression model	**Voluntarily unemployed**	-0.876 (M); -0.213 (F)	<0.001 (M); NS (F)
						Unemployed	2.150 (M); 1.202 (F)	<0.001
						Employed	1	
Gathergood (2012)	UK	1991-2009	107035	Depression (GHQ12)	Regression model	**Voluntarily unemployed**	0.16	NS
						Unemployed	1.05	<0.01
						Employed	1	
Yao and Wu (2021)	USA	2020	1576770	Anxiety (GAD-2)	Odds ratio	**Voluntarily unemployed**	0.948	<0.001
						Unemployed	1.203	<0.001
						Employed	1	
				Depression (PHQ-2)	Odds ratio	**Voluntarily unemployed**	1.123	<0.001
						Unemployed	1.311	<0.001
						Employed	1	

occupational status and presents fair methodological quality (6 points in the NOS scale) [30] and did not assess mental health outcomes through validated tools, but by asking participants if they felt anxious or depressed, this study is therefore not reported in the quantitative synthesis but will be discussed qualitatively.

The three studies synthesized quantitatively reported on mental health outcomes in voluntarily unemployed people, comparing them with employed and unemployed people. This comparison of the results and the main characteristics of the included studies are reported in Table 1.

The best evidence synthesis from the studies included in this systematic review highlighted that voluntarily unemployed participants were more depressed than employed participants in three of the included studies [28-30], while one found they were less depressed [27] (insufficient evidence). All four studies investigating depression highlighted that voluntarily unemployed people were less depressed than unemployed people [27-30] (strong evidence). The two studies investigating anxiety reported that voluntarily unemployed people were less anxious than employed and unemployed people [29, 30] (moderate evidence).

The study performed by Buffel et al [27] in 2015 gathered data from 20 European Union countries from two surveys distributed in 2006 and 2012. The authors evaluated depression in participants using the Center for Epidemiologic Studies Depression Scale (CES-D), on a sample of 51,679 people. The scores of the CES-D were highest in voluntarily unemployed people ("unemployed and not seeking a job"), followed by unemployed and job-seeking participants, and lowest in employed people, meaning that voluntarily unemployed people had the highest levels of depression. Results from the model developed by Buffel et al. comparing these three categories and controlling for the most factors are reported in Table 1 (these results refer to Buffel et al., Table 4, Model 3). Unemployed participants seeking a job were more depressed than employed people, while voluntarily unemployed participants were less

depressed than unemployed people ($p<0.001$ for males, not significant correlation for females).

This study has many strengths: the large sample, the depression assessment is performed through a validated tool, the impact of the economic crisis in many EU countries at the time of the survey was taken into account, and gender differences in depression prevalence are also evaluated. However, the authors acknowledge that the study design does not make it possible to draw final conclusions about causation; furthermore, the cross-sectional design does not allow for the evaluation of the long-term consequences of the economic crisis.

The 2012 research by Gathergood [28] gathered data from 1991-2009 and had 107035 participants from the UK. The authors evaluated depression in participants using the 12-Item General Health Questionnaire (GHQ-12). The GHQ-12 scores of employed participants were compared to the scores of unemployed participants and voluntarily unemployed participants; the results are reported in Table 1. The authors highlighted that unemployed individuals were more depressed than employed people ($p<0.01$); however, despite voluntarily unemployed people being less depressed than employed people (as reported in Table 1), the correlation between voluntarily unemployed participants and the GHQ-12 score was not statistically significant.

Interestingly, the authors measure the variation of the GHQ12 scores in participants who enrolled in multiple waves of the survey distributed in the UK from 1991 to 2009, reporting an increase in the score (meaning the psychological health worsened) of 0.04 for the employed 0.55 for voluntarily unemployed people, and 1.12 for unemployed people, highlighting that unemployed participants are more at risk for the progression of depressive symptoms in the long term. However, the authors acknowledge that the likelihood of becoming unemployed shortly may greatly impact the questionnaire scores, but no questions regarding perceived expectations of unemployment were gathered.

The study performed by Yao and Wu [29] in 2021 in the USA gathered 2020 data from 1576770 participants, evaluating anxiety through the Generalized Anxiety Disorder 2-item (GAD-2) scale and depression through the Patient Health Questionnaire-2 (PHQ-2). The authors highlighted, for anxiety, a decrease in risk for voluntarily unemployed people compared with employed participants ($p<0.001$) and an increase for unemployed people compared with employed participants ($p<0.001$); for depression, an increased risk was highlighted for both voluntarily unemployed and unemployed participants compared to employed people ($p<0.001$), although for unemployed people the risk was higher.

The study, conducted during the COVID-19 pandemic, highlighted that the voluntarily unemployed had lower expectations of job loss in the family (91.09% answered they did not expect job loss in the family, versus 72.41% of working and 45.64% of unemployed people), and had better food security (73.20% reported that food was always enough, versus 62.77% of working and 39.37% of unemployed participants). However, health and access to care were reported as good or excellent by a higher percentage of working people (87.36%) compared to involuntarily (69.86%) or voluntarily (78.82%) unemployed. However, this study had a few limitations: the voluntarily not working participants had a higher mean age (67.04 years) compared to working (43.74 years) or unemployed (44.47 years) participants, and they had fewer children on average (0.25) than working (0.81) or unemployed (0.89) participants. These could have acted as confounding factors in the mental health scores. Furthermore, the COVID-19 pandemic may have affected participants' psychological well-being, which could have worked as an additional confounding factor in the study by Yao and Wu.

The study performed by Aydiner-Avsar et al. in 2021 evaluated anxiety and depression in the USA in 2013 and 2014 by asking the participants if they were feeling anxious or depressed (not using validated tools) [30]. The total sample size was not reported; the authors only reported the number of participants feeling anxious or depressed. The authors highlighted that unemployed men and women reported feeling depressed and anxious more often than employed people ($p<0.001$), while only voluntarily unemployed men reported feeling depressed and anxious more often than employed men ($p<0.001$), but this correlation was not statistically significant for voluntarily unemployed women.

This study has accounted for many sociodemographic factors that may influence mental health in relation to employment status (such as marital status and age) and highlighted the effects of these factors on the mental health of participants, showcasing that older age and being divorced or separated were risk factors for both anxiety and depression. However, as mentioned, the authors did not use validated tools to assess mental health outcomes.

4. Discussion

This systematic review investigated mental health outcomes in voluntarily unemployed individuals. Four manuscripts were included in the review. The studies highlighted that voluntarily unemployed people were less depressed than unemployed but more than employed people, except for one study, which found that they were less depressed than both other subgroups. Furthermore, voluntarily unemployed people were less anxious than employed and unemployed people in the two studies investigating this outcome.

The results of this review are in line with previous literature regarding depression incidence in unemployed people [2, 3, 6]. Voluntarily unemployed people have been highlighted to be less depressed than unemployed but more than employed people. This could be due to the fact that, unlike involuntarily unemployed people, they may not face the same loss in sense of identity, purpose and future vision that has been associated with job seeking unemployment [31]. This could be due to the fact that unemployed people face constant rejection during the job searching process, while voluntarily unemployed people do not have to endure the same straining path, simply by distancing themselves from the occupational world. However, this does not appear to completely erase the negative mental health outcomes associated with job loss, since in three out of four studies voluntarily unemployed people were more likely to report being depressed than employed people. The same sense of identity and purpose loss may therefore apply to voluntarily unemployed people even though they distance themselves from the labor market; the relationship and causation of voluntarily unemployed workers' depression with job loss rather than job seeking should be further investigated.

The results from this review showcased anxiety being reported less often in voluntarily unemployed workers. This is consistent with previous literature, which has highlighted that anxiety in workers tend to be correlated with job insecurity and uncertainty about the future [32, 33]. It seems consequential that, in voluntarily unemployed people that are not seeking employment in the near future, anxiety does not play an important role in their psychological wellbeing. Furthermore, considering voluntarily unemployed as people who have distanced themselves from the occupational world, it could be that anxiety lessens over time. In further research, an evaluation of anxiety in people who have recently left the job market as opposed to people who have been outside it for a longer time could help understand if this hypothesis is true.

Moreover, the home country's economic status may play an important role in mental health outcomes related to occupational status. Buffel et al highlighted that in countries with worse economic crises, the gap in depression between voluntarily unemployed and unemployed people became larger [27]. The authorssuggest that this may be because seeking a job during a recession is harder, and this could affect unemployed people negatively; on the contrary, voluntarily unemployed people may feel less stigmatized during a recession if lay-offs increase and more people are in the same situation of unemployment, whether voluntarily or not. The relationship between mental health outcomes in voluntarily unemployed people and the economic status of the country – in addition to personal economic status – could be investigated in future studies to assess the influence of country-scale economics on the mental health of people who choose not to seek employment. This would be especially interesting in the current occupational landscape, considering the surge in resignations registered during the COVID-19 pandemic [34, 35].

Two of the studies included in this systematic review highlighted that voluntarily unemployed men are significantly more depressed and anxious than employed men, while this correlation was not significant in women [27, 30]. This is consistent with previous literature findings regarding unemployed men [10, 11]. In future studies, it would be

interesting to further analyse gender differences in voluntarily unemployed people to assess if the relationship between gender and mental health is consistent and if it is similar to that of unemployed people.

A higher risk of depression and anxiety has been showcased in older, voluntarily unemployed people [30], and depressive feelings have been reported to progress more in the long term in unemployed people [28]. This is also consistent with previous literature [5-9]. As voluntarily unemployed people are harder to reach and are not surveilled by occupational physicians, a progression of negative mental health outcomes in time may be difficult to recognize and prevent. Underlining a progression over time highlights the importance of reaching and leading back into the occupational world voluntarily unemployed people who may have been discouraged from seeking occupation in a prompt and timely manner to ensure that negative mental health symptoms can be recognized early and this progression can be prevented.

As emerged from this systematic review, the literature currently available focusing on the issue of voluntarily unemployed people is scarce, and even for the studies included in this review, the main focus was unemployment and mental health, with the voluntary or involuntary status being investigated through one item in which the participants expressed they were not seeking employment at the time.

Further research should investigate the sociodemographic characteristics of people not seeking employment to establish the causes of the voluntarily unemployed people's alienation from the occupational world and their perspectives while living outside of the labour market – and therefore, supposedly without a fixed income. Furthermore, this population subgroup should be investigated to establish strategies to ease young people's transition into the labour market or lead voluntarily unemployed back into the occupational world.

This review has some strengths, as it was carried out following the PRISMA guidelines and using a systematic methodology; it includes studies performed over an extended time period (ten years) that took into account the changes in the economic climate during the data gathering period. However, it also had a few limitations. Due to the scarcity of studies performed on this topic, only 4 studies were included in the review; furthermore, the heterogeneity of the tools used to assess mental health outcomes in the three included studies that used validated tools did not allow the researchers to perform a meta-analysis.

5. Conclusion

Three of the four studies in this systematic review highlighted that voluntarily unemployed people were less depressed than unemployed but more than employed people; the fourth study highlighted that they were less depressed than both. Furthermore, voluntarily unemployed people were less anxious than employed and unemployed people in the two studies investigating this outcome.

The available literature on this issue is poor. Further research should investigate the causes of negative mental health outcomes in voluntarily unemployed people and strategies to bring back, when possible, these individuals into the workforce.

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The Challenge of New Forms of Work, Innovative Technologies, and Aging on Decent Work: Opportunities for Occupational Safety and Health*

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Summary

Occupational safety and health (OSH) can be relevant in achieving the United Nation's Sustainable Development Goal of decent work by 2030. However, further OSH actions are needed. This paper identifies the role of OSH in addressing two of many determinants of decent work: new forms of work/innovative technologies and worker aging. The authors conducted a discursive analysis of the two determinants and provided examples for consideration. New forms of work and innovative technologies can not only promote but also undermine the future of decent work, and unhealthy aging impedes longer working lives. With a focus on the OSH aspects of new jobs, innovative technologies, and aging, decent work is more likely to be achieved.

1. Introduction

The scientific literature has increasingly corroborated the relationship between decent work and occupational safety and health (OSH) [1-6]. However, progress toward achieving the United Nations' Sustainable Development Goal 8 on decent work and economic growth has not been fully realized, and further efforts to identify OSH actions are needed [7]. To this end, we developed a staging framework and conducted a discursive investigational process to expand the focus of OSH toward decent work. The framework is a matrix, with the x-axis containing the four International Labour Organization (ILO) principles of decent work (employment creation, social protection, rights of workers, and social dialogue) and the y-axis addressing eight determinants of decent work [new (innovative) technologies and

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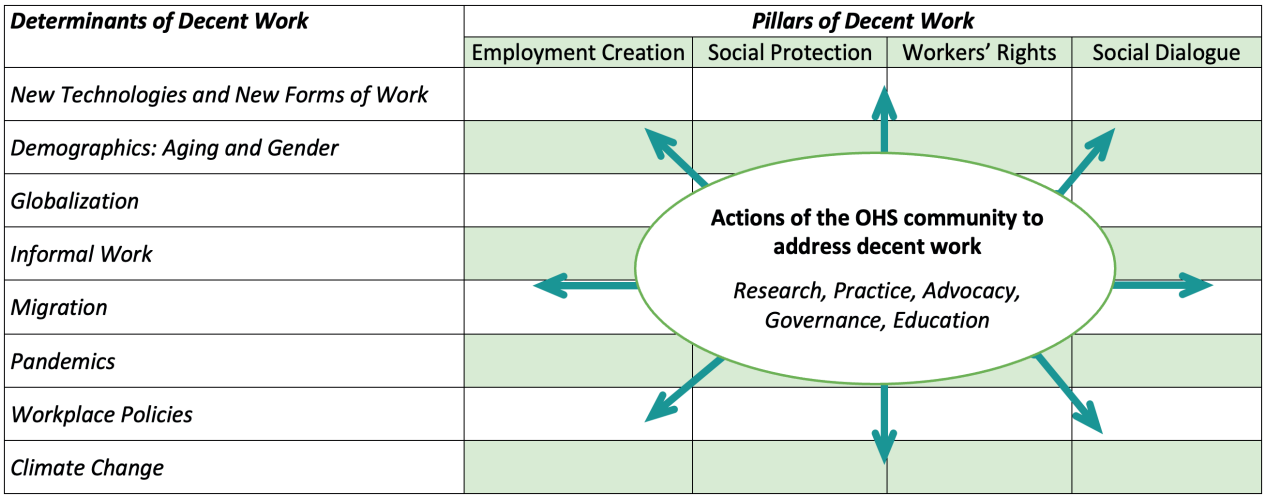

Figure 1. Framework to expand the role of OSH to achieve decent work. Adapted from ref. [4]

new forms of work, demographics (aging and gender), globalization, informal work, migration, pandemics, OSH policies, and climate change] (Figure 1).

To help address the cells in the matrix, we reviewed the impediments and recommendations for achieving decent work in each of the primary function areas of OSH (research, practice, advocacy, governance, and professional education). This paper addresses new forms of work and innovative technologies regarding the pillars of decent work, particularly social protection and workers' rights. We then focus on a demographic determinant—aging—and its relationship to decent work. Aging is a critical determinant of decent work since the world's population is aging [8].

This paper aims to illustrate how two determinants from the framework—*new forms of work and innovative technologies* and *aging*—affect decent work from an OSH perspective. We chose these determinants because they represent our interests as authors and researchers and address the first two rows in the framework. Moreover, they represent significant determinants of decent work. These two determinants reflect changes in work and the workforce—critical aspects of the changing world of work. These changes challenge the OSH field and impact the realization of decent work. Work cannot be decent when workers die or become ill, injured, or disabled. Recent statistics indicate that 2.9 million workers die every year globally from work-related diseases and that 0.32 million of these deaths are due to occupational injuries [9]. Thus, the field needs to know how work and the workforce change and can influence these statistics. This paper is designed to contribute to that awareness.

However, the OSH scientific community needs to turn its attention not only to new technologies and new forms of work and aging but also to other determinants that can impact health and safety in the workplace, such as gender, globalization, migration, climate change, informal work, OSH policies, and pandemics [4]. All these factors also influence the implementation of decent work, defined by the ILO [10] as follows:

> Decent work sums up the aspirations of people in their working lives. It involves opportunities for work that is productive and delivers a fair income, security in the workplace and social protection for all, better prospects for personal development and social integration, freedom for people to express their concerns, organize and participate in the decisions that affect their lives and equality of opportunity and treatment for all women and men.

OSH is one of the foundational elements of decent work. Aspects of OSH are characteristics of each ILO pillar of decent work. For example, employment creation addresses worker training, unemployment, and underemployment; social protection includes OSH and good working conditions, work hours, and work-life balance; workers' rights underpin OSH and include refusal of unsafe work, safe work standards, and dignity and equality; and social dialogue promotes workers' voices and communication between workers and employers.

To understand the relationship between OSH and decent work, it is helpful to remember that the main objective of OSH is to eliminate adverse effects on workers' health, particularly occupational diseases and accidents at work, following exposure to risks in the workplace. To achieve this objective in daily practice, the OSH system uses among various approaches, a traditional approach that relies on the classic model of occupational risk assessment developed more than 40 years ago by the US National Academy of Sciences [11].

In the last few decades, numerous technological discoveries have also begun impacting the world of work with consequent changes in work processes, which have become more efficient, resulting in new forms of work. Accordingly, OSH needs to keep up with these changes in the world of work to adequately address the resulting new occupational risks and any effects on workers' health [12].

2. New Forms of Work: Overview

Over the last decade, Industry 4.0 has expanded to include new forms of work. This term describes an innovative concept relevant to implementing and integrating novel high-tech strategies and tools in production systems to "digitally connect everything in and around a manufacturing operation in a highly integrated value" [13, 14].

The aim of Industry 4.0 is to achieve high productivity and flexibility by transforming industrial manufacturing processes through greater automation and computerization. Available evidence suggests that Industry 4.0 might be associated with several OSH issues and concerns, such as work-related psychosocial hazards and privacy invasion [14]. The spread of Industry 4.0 also has implications for decent work. For example, regarding *employment creation*, automation, and computerization are, on the one hand, eliminating some low-skilled and more repetitive jobs and, on the other hand, necessitating new jobs that require specific skills related to the continuous technological evolution of Industry 4.0. In this context, the role of OSH is fundamental to guarantee a transition that protects workers' health as much as possible. Indeed, while eliminating repetitive and low-skilled jobs can reduce the accident phenomena related to this type of work, Industry 4.0 likely has a high psychosocial impact on many workers and involves the acquisition of specific skills, which bring new related hazards and risks [14].

The European Union has begun to address the limits of Industry 4.0 by proposing the transition to Industry 5.0, which is more sustainable, human-centric, and resilient [15]. Industry 5.0 places the well-being of humans at the center of production systems to go beyond employment and growth to the robust delivery of prosperity for the sustainable development of all humanity [16]. Thus, Industry 5.0 also supports *social protection*. Precisely for this reason, it is necessary to guarantee *workers' rights* by developing policies and guidelines to ensure workers' protection when the Industry 4.0 paradigm is implemented. Furthermore, to provide *social dialogue*, it is crucial to facilitate workers' active workplace participation in the processes used to identify, evaluate, and manage the new hazards introduced by Industry 4.0, thereby enacting a bottom-up approach and considering all possible stakeholders.

In conclusion, innovative technologies and new forms of work can not only promote but also undermine the future of decent work. Accordingly, all involved stakeholders (i.e., practitioners, researchers, advocates, policymakers, governments, and educators) need to take concerted actions to critically identify OSH challenges related to decent work. Active policies, analysis methodologies, intervention strategies, and operational tools (within OSH's competence) capable of facilitating the realization of decent work should be implemented through an integrated and multidisciplinary approach. To do so, OSH professionals' perspectives and expertise

should be considered in decision-making, leading to developing policies that will fully realize decent work.

2.1. Innovative Technologies

Two examples of innovative technologies will be discussed in this paper. In this section engineered nanomaterials (ENMs) will be discussed. Later in the section 3, innovative technology in the transportation sector will be addressed.

An example of new technologies is the introduction of nanotechnologies into the world of work, as exemplified by ENMs. Currently, ENMs are widely developed, produced, and marketed. This situation has inevitably led to increased human exposure, particularly among workers involved in the entire ENM life cycle of development, production, processing, elimination, and recycling [17]. ENMs can be absorbed through various routes (mainly pulmonary and dermal). They can induce various morphological and functional changes, resulting in negative impacts on the nervous, respiratory, cardiovascular, renal, immune, and endocrine systems, as demonstrated in both *in vitro* and *in vivo* studies [18, 19, 20]. Despite these issues, a systematic and comprehensive risk assessment of these potential hazards still needs to be performed [65]. This lack of a risk assessment inevitably impacts the first pillar of decent work. Although the widespread diffusion of ENMs has created and is still offering employment opportunities and nano-enabled job tasks, the issue of *employment creation* cannot be approached only in quantitative terms but also needs to be approached, above all, in qualitative terms. Ensuring decent working conditions that prevent workers' exposure to uncontrolled hazards and risks is necessary.

In the OSH context, the impact of new technologies can be addressed by implementing the precautionary principle, publishing and disseminating best practices and recommendations to evaluate and manage ENMs in workplaces, and guaranteeing *social protection*. This approach can also be used for other new and emerging risks [4]. For example, *workers' rights* can also be guaranteed in the presence of new and emerging risks with uncertainty surrounding their extent and severity through applying prevention and protection measures via engineering and administrative controls and personal protective equipment.

However, ENMs are a considerable challenge in *social dialogue* due to the significant uncertainty about their hazards, risks, and burdens. In this case, OSH professionals can be crucial in facilitating dialogue between social partners, especially by raising awareness and avoiding underestimating the risks. Nevertheless, field research using a participatory approach to engage with stakeholders is needed to identify adequate data communication and transferability strategies. In this context, it is essential to communicate to employers, workers, and government representatives the potential safety and health risks associated with new and emerging hazards in the workplace and to implement practical and innovative training and education programs for employers, workers, and OSH professionals aimed at increasing their knowledge and awareness of ENMs.

2.2. Social Protection in Anticipating New and Emerging Risks

Decent work is fundamental to supporting inclusive and sustainable economic growth and achieving total productivity [21]. However, new technologies and new forms of work have induced significant morphological and functional changes among workers [22-24]. These changes are driven by new and poorly understood physical and chemical risks, which are often also associated with environmental degradation and the use of nanomaterial engineering in production processes [4, 21, 23]. Although these advances can potentially improve working conditions, they pose significant challenges and uncertainty.

Understanding the new hazards introduced by these technologies is crucial to ensuring workers' safety and promoting healthy work environments. ENMs represent a significant concern among these hazards due to their unique properties and the potential for unknown health impacts [25]. Additionally, Industry 4.0 has impacted work organizations, which may increase psychosocial risks and lead to increased injuries and diseases at the interface with

automated devices, introducing a range of emerging physical risks that must be carefully evaluated [26]. Furthermore, the evolving nature of work environments, such as informality and platform work, can cause psychosocial risks that negatively affect workers' mental health and well-being [1].

2.3. Future Directions and Challenges to Ensure Social Protection

Future work should prioritize workers' well-being, with the pillar of social protection playing an indispensable role in this effort [4]. Ensuring workers' safety, health, and overall well-being in rapidly evolving work environments and technologies is a multifaceted challenge that requires robust social protection mechanisms. These mechanisms should encompass OSH research practices to maintain safe working conditions, provide adequate rest periods, and ensure access to essential benefits.

Different contexts present varied challenges. In high-income countries (HICs), the complexities of intersectionality—that is, how various social categorizations (e.g., race, gender, and socioeconomic status) intersect and impact individuals' experiences—present unique challenges [27]. Addressing these intersectional issues ensures workers equitably benefit from the work environment and technology advancements.

In low- and middle-income countries (LMICs), the challenges are more pronounced in terms of vulnerable groups and the widespread impacts of informality [28]. Informal workers, who often lack access to essential social protection and tend to work in hazardous conditions, represent a significant portion of the workforce in these regions. Ensuring their safety and well-being requires specific interventions that address their particular vulnerabilities and the precarious nature of their work [4].

Social protection should evolve to anticipate future work's new and emerging risks. This evolution includes proactively identifying categories of vulnerable workers and specific groups and understanding how variability in worker-technology interactions can affect health and safety [4, 22]. By focusing on these aspects, social protection frameworks can be better equipped to effectively mitigate new and emerging risks.

Mitigating these risks involves a nuanced understanding of how workers interact with new technologies. For example, workers in HICs may face risks related to technology's complexity and rapid evolution. In contrast, workers in LMICs may be more vulnerable to primary safety risks due to a lack of infrastructure and regulatory oversight. Adapting social protection measures to address these diverse needs is crucial to promoting safe and healthy work environments globally.

Additionally, introducing new workplace risks has profound psychosocial implications for workers. Income instability and uncertainty regarding the availability and continuity of work significantly affect mental health. Studies have shown that economic uncertainty can lead to increased psychological distress, anxiety, and depression [29]. Similarly, job insecurity, a predominant issue in many modern work environments, is closely associated with reduced well-being, leading to decreased job satisfaction and increased absenteeism and turnover rates [30]. Moreover, job insecurity can exacerbate psychosomatic complaints, such as physical tension and other stress-related symptoms, further affecting workers' overall health and productivity.

2.4. Recommendations Regarding Social Protection

How can social protection practitioners and advocates anticipate the unknown effects of new risks and damages? The following discussion addresses some strategies for predicting and mitigating these effects.

2.4.1. Development of Transdisciplinary Skills and Training

One crucial strategy involves the development of transdisciplinary skills and training programs. These initiatives should equip workers and managers with the knowledge and skills to anticipate and address poorly understood risks. By fostering a holistic understanding of potential hazards, such training can enhance workers' ability to navigate complex work

environments safely. Such training should address the intricate interplay of workers' physical, chemical, and psychosocial risks, promoting a comprehensive understanding of workplace safety and health [31, 32].

2.4.2. Identification of Vulnerable Worker Categories

As another strategy, it is imperative to identify and support vulnerable worker categories and specific groups that may be disproportionately affected by new risks. Such groups include low-wage, informal, older, and women, who often face unique challenges adapting to new technologies and working conditions. Tailored social protection measures can help mitigate the impacts on these groups [4].

2.4.3. Understanding the Variability in Worker–Technology Interactions

The following strategy involves deeply understanding how different workers interact with new technologies. It consists in studying the variability in these interactions to develop targeted interventions that ensure the safe and effective use of new technologies across diverse work environments [33].

2.4.4. Expanded Coverage Network

The final strategy involves expanding OSH's coverage to include workers in the informal sector. Informal workers often lack access to basic social protection and are particularly vulnerable to new risks. By extending coverage and benefits to this workforce segment, social protection systems can provide a safety net supporting workers' health, well-being, and economic stability [34, 35].

3. An Example of an Innovative Technology: Artificial Intelligence

3.1. "Cobots" and the Rights of Workers

Artificial intelligence (AI) is making sweeping inroads in the workforce, as evidenced most recently by the extensive use of large language models, including generative AI. While AI creates tangible benefits for workers, there are also emerging physical and psychosocial risks to a safe, healthy, decent working environment. A recent literature review on workers and workplace AI highlighted four areas: (i) can workplace AI augment workers' abilities? (ii) can workers' distrust in AI due to their concern that it will replace their jobs be addressed? (iii) will the loss of noncritical skills impact workers' performance on the job? and (iv) can the teaming of AI and workers be implemented successfully (what we refer to as human-robot teaming, or "cobots") [36]? Below, we describe how these issues relate to a safe, healthy, and decent workplace, focusing on the transportation industry.

3.2. The Benefits of AI: The Example of the Transportation Sector

In the transportation sector, AI can benefit operators' safety, regardless of whether an operator is driving a passenger car, a transit bus, a plane, or a truck. For example, ride-hailing "gig" workers typically drive vehicles with advanced driver assistance systems. The safety benefits of two such systems—automatic emergency braking and lane departure warnings—have been shown conclusively to save lives [37, 38]. Additionally, just as passenger car drivers have been shown to benefit from backup cameras, so too have heavy equipment operators [39].

AI also has benefits for workers' health in this sector. As an example of how AI can improve transportation workers' health, consider parking decisions for commercial motor vehicle (CMV) drivers. The American Trucking Research Institute's recent survey ("Critical Issues in the Trucking Industry") rated truck parking as the second-highest concern among CMV drivers and the eighth-highest motor carrier concern [40]. AI and machine vision are already used to help drivers find parking locations in seaports [41]. Phone applications are being developed to help CMV drivers locate parking destinations that allow them to meet hours-of-service requirements, include amenities that meet their needs, and are safe and easily accessible. Indeed, according to the National Transportation Safety Board, fatigue is the likely cause of more than half of all truck crashes that result

in a driver's death [42]. Thus, the ability to find safe and accessible parking efficiently is a priority for the Federal Motor Carrier Safety Administration.

Finally, AI is being used to increase decency in the transportation sector. For example, inspection programs for CMVs should be considered. The purpose of regular truck inspections is to ensure trucks are safe for people to continue operating them. However, like other scenarios in which trained inspectors and law enforcement officers interact with the public, inspections may be subject to biases. Specifically, past research has indicated that implicit biases play a role in police inspections and enforcement actions for motor vehicles [43]. AI could reduce these biases, especially for inspections centered on the condition of truck tires since it is challenging to decide how severe the cut and mechanical separations are on various types of tires [44].

3.3. Trust and AI

Workers' distrust of AI due to potential job loss has been identified as a serious problem [36]. This problem can be exacerbated through over- or under-trust in the actual functions of AI. Both situations can impact workers' safety. In the transportation sector, this problem is most evident in vehicles described as self-driving. A recent field experiment demonstrated the lethal consequences of over-trust in these vehicles [45]. Drivers navigated a 30-mile course with a Level 2 vehicle (i.e., a car with at least two primary functions automated). Drivers were given both an attention reminder and a hands-on-wheel reminder.

Additionally, the drivers were shown videos regarding risk scenarios, including a video showing a car starting to depart from the roadway, which the driver needs to steer back before letting the function resume. Finally, the drivers were told that the automation does not detect obstacles in the roadway, so they must brake and/or steer away from obstacles and then let the function resume control. During the experiment, a dummy car or trash bag was placed along the roadway without informing the test drivers. The results were unexpected as even after the extensive warnings about the limitations of the automation, one out of every three drivers hit the stationary car or trash bag.

Under-trust in AI can be problematic if operators deactivate warnings to decrease safety-critical events. In transportation, lane departure warnings are one example. Because lane departure warnings are frequently false positives, drivers often deactivate them. In one study, only 45% of vehicles with lane departure warnings had these systems activated [46]. However, at least for heavy trucks in the United States, roadway departures account for 35% of all crashes.

3.4. Skill Loss

By design, AI complements and sometimes replaces workers' skills. This practice can compromise safety in ways that are not predictable but can have major consequences. As AI performs more aspects of a task, the focal worker is left with only high-level situational awareness of what might happen. However, if some lower-order process within the task fails, real problems can occur—something that has been researched extensively in aviation [47]. This issue is especially problematic if the worker has lost the ability to perform the skill automatically and instead has to fall back on the knowledge of how the skill is performed [48]. In transportation, such situations may arise with drivers of electric vehicles. Electric vehicles have a one-pedal operation, which means the accelerator pedal can function as a typical accelerator and a brake to slow the car rapidly, just as typical braking would. One-pedal operation is especially useful in electric buses because it further increases energy efficiency by managing the regenerative braking operation [49]. From a human factors perspective, when returning to driving a two-pedal internal combustion engine vehicle, operators of one-pedal electric vehicles are likely to forget to brake in an emergency and release the accelerator. Although this has not been studied formally, one-pedal electric vehicle operation in transportation could make currently unlikely crashes much more likely.

3.5. Cobots: Human-Robot Teaming

Next, consider successful teaming—in our case, successful cobots. A 2023 article in *Harvard Business Review* argues that three things mark

high-performing teams: a shared understanding of each other's roles, psychological safety or trust, and prosocial service or, in this case, shared fate [50]. First, for a common understanding, every team member should understand how their expertise and job duties contribute to the bigger picture (i.e., to the team's and respective organization's performance). Cobot vehicles (i.e., vehicles with driving automation systems) do not have this capacity. Most drivers do not understand how their expertise contributes to the expertise of the automation—for example, that the automation cannot "see" a stopped vehicle. Currently, automation, at least as embodied in driver state monitoring systems, does not truly understand how its expertise is needed to maintain drivers' attention—for example, drivers need to be warned when a hazard appears, and they are not attending to it. Second, psychological safety occurs when team members feel safe expressing themselves, speaking up when they have questions or concerns, disagreeing with each other, making mistakes, and taking interpersonal risks. Again, this is not the case with the current cobot paradigm. However, research on crew resource management in the airline industry indicates that the pilot and copilot need to be a team and build trust so the copilot can let the pilot know when they think there is an error the pilot has not recognized. The pilot has faith in the copilot and pays attention. In the context of cobot vehicles, warning systems need to learn from drivers when alarms are false, and drivers need to learn why warning systems are giving particular warnings. Currently, drivers provide no information to warning systems, and warning systems provide no information beyond warnings to drivers. However, when such information is given, this communication can lead to psychological safety. Large language models could be helpful here for learning from and teaching drivers. Finally, prosocial service in terms of a shared fate involves a deeper level of trust on the part of humans. The Trolley problem is a good example here. In one version, a runaway trolley is on course to collide with and kill several people (traditionally five) down the track. Still, a driver or bystander can intervene and divert the vehicle to kill just one person on a different track. Regarding prosocial service, the driver needs to know their response and how the automation would implement that response.

3.6. Summary of AI in the Transportation Sector

In summary, workers need to (as much as possible) be fully capable of performing all of the technical and conceptual tasks involved in their jobs, especially those aspects that are performed infrequently (i.e., those performed primarily by AI) and could cause critical safety events. If workers cannot perform these tasks (i.e., there is no true teaming with AI), the safety and health risks are considerable, as detailed above. Here, very briefly, we want to address how AI could lead to a workplace that is not decent for workers if AI is introduced without care.

The most considerable risk arises in human resources and performance evaluations. One example outside of transportation is the Horizon Post Office scandal. In that case, prejudicial AI systems wrongly identified and harassed people as potentially having been involved in one or more illegal actions [51]. In transportation, biases could be introduced in the hiring process, performance evaluations, and, potentially, CMV inspections [52]. Thus, individuals involved in hiring and performance evaluation processes must be aware of the potential biases in seemingly unbiased algorithms.

4. Decent Work and Aging Workers

Another determinant of decent work is aging. Like new forms of work and innovative technologies, aging is critical in realizing decent work.

4.1. Early Aging at Work

The definition of an aging worker is generally based on the period when significant changes occur in relevant work-related functions during a person's work life. While the ages of 40 or 45 were typically used as benchmarks for considering a worker to be older in the past [53], age references are currently on the rise to 50, 55, or 60, reflecting not only the aging of the labor force but also the increase in the legal retirement age [54].

Biological aging is a dynamic and progressive process characterized by morphological, functional, biochemical, and psychological changes. These modifications lead to the progressive loss of the ability to adapt to one's environment, causing greater vulnerability, increased incidence of pathological processes, and a gradual decrease in functional capacity [55].

As workers get older, interindividual variability increases, so it becomes possible to identify people with functional and work-ability limitations at an early age. In many cases, some of these processes of functional incapacity are related to occupational exposure [53, 56].

4.2. Changes During the Aging Process

Negative changes during the biological aging process may include increased morbidity burden, decreased functional capacity, reduced musculoskeletal capacity, lowered cardiovascular and respiratory efficiency, reduced motor functions, reduced sensory functions (visual and auditory acuity), increased sleep disorders, the need for more recovery time between shifts/workdays, diminished cognitive capacity for information processing and the memory system, and decreased competence to master new types of mental tasks and new concepts [57, 58].

Positive changes can also occur, including enhanced critical thinking, judgment, and decision-making capacity; increased ability to understand the whole; more empirical knowledge, life experience, and wisdom; increased ability to solve complex problems based on experience, knowledge, practice, and diligence; commitment to quality, health, and safety at work; strong understanding of one's company and loyalty/commitment to one's institution; lower turnover and lower absenteeism; strong language and communication skills; independence; increased responsibility and social competence; leadership skills; and greater motivation to learn [53, 56-58]. All of these changes can influence individuals' work ability and functional aging at work, both positively and negatively.

4.3. Constraints to Decent Work

The global population is aging, which demands and will continue to demand longer working lives. To enable people to remain at work, decent work must support workers to maintain employment as they age. However, participation in work requires workers to be sufficiently healthy. Disability from work occurs not only from the aging process but also through exposure to adverse work environments [59, 60].

Thus, using a system thinking lens, analyzing the micro (individual), meso (work), and macro (societal) impacts on individuals' health outcomes provides a way to consider potential actions to enable sustained working lives for all workers, including those who are older [8, 57, 61-63]. This perspective is crucial when looking at changes in the global economy and its enormous impact on labor markets. It is vital to strengthen positive early employment trajectories and explore the influence of contextual factors on individuals' working life experiences starting at a young age [64].

4.4. Actions for Healthy Aging at Work

As discussed earlier, the OSH framework for decent work proposes four pillars: employment creation, social protection, worker rights, and social dialogue. It also introduces eight determinants that intersect with each pillar, including new technologies and new forms of work, demographics (aging and gender), globalization, informal work, migration, pandemics, OSH policies, and climate change [4].

One challenge for the OSH community working to promote sustained employment is developing practical actions to support longer working lives. Therefore, actions must be taken across the life course, and a systems model must be utilized to maximize their effectiveness.

Actions to promote workers' capacity, prevent early functional aging at work, and treat and support workers who are already compromised and those with disabilities and limitations cannot be limited to older workers [57, 62]. These actions must be implemented at three levels—the micro, meso, and macro

levels. Below, we briefly highlight proposed actions at each level.

At the micro (worker) level, a systems analysis of the drivers of sustainable employment is needed, with a particular focus on older workers. Moreover, longitudinal research is required to examine the relevant influences related to sustainable working conditions, to investigate workers' needs throughout their working lives, and to identify critical periods. Comprehensive risk assessments of work environments also need to include coverage of physical and psychosocial hazards to ensure prevention strategies can be implemented early. Further, older workers need to be engaged in planning their jobs to provide a good match between their capacities and their job requirements and to ensure disabled yet productive aging workers are integrated into the workplace. Finally, work systems need to be analyzed to make sure they consider the limitations and capabilities of workers as they age.

At the meso (workplace) level, new technologies must be implemented to improve the coupling between humans and work systems and increase the integration of disabled and older workers. Further research is needed to investigate the impact of automation on the creation of high-quality jobs aimed at preventing disabilities and to explore virtual reality to promote new forms of work for disabled and aging workers. Finally, the systems design perspective needs to consider workers' mental health, the potentials and pitfalls of new challenges need to be further explored, and work systems that integrate human factors and ergonomic principles need to be promoted.

At the macro (social) level, organizations need more guidance on creating sustainable working conditions by improving their management of physical and psychosocial hazards. They also need support to ensure disability protection for productive aging workers and to ensure disability protection throughout individuals' entire working lives. Further, organizations must promote lifelong learning programs to empower workers and disseminate information about labor rights and social resources. They can also support initiatives by workers' representatives and encourage and participate in forums with government representatives, employers, and civil societies. Additionally, the OSH framework can be used to identify and implement appropriate actions to support the creation of sustainable employment across the life course to encourage and enable older workers to remain at work [33].

Overall, researchers, practitioners, advocates, policymakers, and governments need to take action to address all system levels—micro, meso, and macro—to ensure an appropriately targeted and comprehensive set of strategies is developed and implemented.

5. Conclusion

This paper illustrates the opportunities for OSH to address two determinants of decent work: innovative technologies/new forms of work and aging. In both cases, OSH resonates with the pillars of decent work to protect workers and enhance their opportunities to achieve decent work.

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Occupational Safety and Health of Riders Working for Digital Food Delivery Platforms in the City of Milan, Italy*

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Abstract

Background: *The rapid growth of the digital economy has transformed various labor markets, including the food sector. The transient nature and the peculiar work environments of food delivery workers raise concerns about occupational safety and health (OSH). This study aims to better understand these issues by conducting a comprehensive exploratory survey on OSH among food delivery riders in Milan, Italy.* **Methods:** *The study employed structured interviews based on a validated questionnaire developed through a literature review, expert interviews, and input from riders and health and safety professionals. The survey was performed from July to November 2022 by interviewing riders at their main gathering points.* **Results:** *We interviewed 240 riders, 97% males, 81% less than 35 years old, and 83% with extra-European origin. Delivery was performed mainly by traditional bicycles (40%) and e-bikes (46%), with 44% working seven days per week and 23% working more than 8 hours daily. Overworking was significantly influenced by the type of contract, citizenship, and platform. Road accidents were reported by 39% of riders, influenced by type of vehicle, fatigue, and number of daily deliveries. Physical and verbal assaults (12% and 28%, respectively) were reported, as well as health-related issues, particularly musculoskeletal disorders.* **Conclusions:** *The findings underscore food delivery riders' complex challenges, emphasizing the need for targeted interventions. The study calls for collaborative efforts between policymakers, employers, OSH professionals, and stakeholders to enhance OSH standards and promote decent working conditions, aligning with the 2030 Agenda for Sustainable Development.*

1. Introduction

The rise of the digital economy has transformed the labor market, presenting new opportunities and challenges for workers globally [1]. Recently, the spotlight on the food delivery sector, enhanced by the COVID-19 pandemic, has favored public discussions about the well-being of "riders", workers employed by digital platforms to transport and deliver goods using various modes of transportation. In Italy, on-demand food delivery is increasing, with a workforce of approximately 60,000 riders, marking a five-fold surge since 2019 [2]. This growth has been even higher in urban centers

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like Milan, Italy, where approximately 8,000 riders are employed.

Given work's transient and dynamic nature in the platform economy, the research has focused mainly on employment relationships [3]. Food delivery platforms have adopted various work organization structures in response to numerous legal complaints and evolving legislation. One standard model is the "free login" system, which offers flexible work schedules without fixed shifts, allowing riders to choose their availability. This is the case for Deliveroo, Wolt, and Uber Eats [4-5], which mostly employ riders as autonomous or temporary workers. In contrast, Just Eat [6] uses a shift-oriented model with subordinate employment, organizing riders in local teams weekly. Glovo and Foodora also use a shift-like model, but they rely on self-employed or temporary workers, with shifts booked in advance by riders according to the so-called "excellence scores" [7-8]. The score is determined by an algorithm that evaluates riders' performances based on availability during high-demand slots, shift cancellations, customer reviews, and total orders delivered. In Italy, riders are classified as self- or para-subordinate employees, with minimum protection levels typical of subordinate employment recently extended to these workers by legislative changes (Legislative Decree 81/2015; Law 128/2019). Differences between contracts affect minimum wage standards and the availability of benefits like sick leave and holidays.

Riders face occupational safety and health (OSH) risks similar to contingent work risks [9]. While the sector offers job opportunities and flexibility, recent research has highlighted issues such as labor control, overworking, and psychosocial implications [10-14]. Riders performing their tasks in urban environments on bicycles, e-bikes, and other poorly protected means of transportation are at risk of road accidents and injuries [15-19]. Besides, there is growing concern about health issues such as musculoskeletal disorders (MSD) [20].

The OSH landscape for food delivery riders is complex, involving multiple factors, including vulnerabilities associated with the transient nature of gig economy work and the prevalence of migrant workers [21]. Despite the increasing interest in rider health and safety, only some studies have systematically investigated this topic [22]. This study aims to fill this gap by examining OSH risks among 240 riders working for food delivery platforms in Milan, one of Europe's most populated (1.4 million people) metropolitan areas.

2. Methods

2.1. Questionnaire Definition and Evaluation

The survey was conducted in a group of riders working for food delivery platforms in Milan through structured interviews administered by a team of researchers. This investigation, performed between July and November 2022, used a questionnaire developed through a detailed process. Initially, a bibliographic review was conducted using the SCOPUS database, focusing on road accidents [15-18, 23] and OSH in platform and gig economy [9-11, 24]. The research extended to "gray" literature, collecting institutional documents [2, 12, 25-27]. Additionally, one food delivery rider and a bike courier, both acting as experts, were interviewed to identify critical topics. Their input informed the draft questionnaire, which was evaluated for content validity and clarity [28-29] by eight experts, including health and safety professionals, labor law experts, and academic researchers. Experts rated each item's relevance and clarity, suggesting modifications as needed. Details on the evaluation method and results are available as Supplemental materials (S1). After the evaluation, changes were made to improve the questionnaire's clarity, simplify its structure, and incorporate new topics. Two previously interviewed workers reviewed the draft questionnaire for additional recommendations. The final version included 38 mandatory items plus 11 optional items (S2), the latter submitted only to riders available to extend the interview owing to the generally tight timeframes for field interviews. Two versions were prepared: paper-based and online using Google Forms. In July 2022, a pilot test with 30 riders ensured the timing and evaluated any ambiguous questions. Following this, a debriefing increased confidence and produced the first feedback; the main was to create an English version of the questionnaire to minimize language misunderstandings with foreign workers. This paper focuses on a subset

of the data related to sociodemographic information, work organization, and OSH risks. The project and the questionnaire were approved by the Ethics Committee of the University of Milan (approval n. 42/22).

2.2. Administration Phase

A team of 10 researchers and students from the University of Milan was selected as interviewers. Two preparatory meetings were held to discuss the questionnaire, interview techniques, and administration methods, including targeting meeting points where riders usually gather (e.g., near restaurants or rail or metro stations). The supplemental material contains a map and a list of these points (S3). The items were not modified. The core survey was performed from mid-September to the end of November 2022. Recruitment and administration took place in the field, with the research team conducting 165 interviews and collecting 75 self-administered questionnaires during four formal Confederazione Generale Italiana del Lavoro (CGIL) trade union meetings, all under the supervision of a researcher. In all cases, the project aims and questionnaire contents were presented before asking for the workers' availability.

2.3. Data Management and Analysis

All the answers to the questionnaire were registered on the Google Forms platform. The probabilities of overworking (defined as working seven days per week or for more than 8 hours per day), road accidents, and health outcomes (e.g., back pain and shoulders/neck pain) are quantified using crude odds ratios (OR) and 95% Confidence Intervals (CI) computed through logistic regression. After univariate analysis, we focused on variables with substantial effect sizes and those relevant to prevention strategies. Multiple imputations addressed missing data, and adjusted O.R.s (AORs) were computed through multivariable logistic regression. Potential confounders for selected exposure variables were identified using directed acyclic graphs (DAG). Descriptive statistics and regression analyses were conducted in R studio [30]. Imputation analysis was conducted using the Mice package [31].

3. Results

3.1. Sociodemographic and Work Information

The study group consisted of 240 riders who were interviewed; their main characteristics are summarized in Table 1.

Most of the interviewed subjects were males of foreign origin without Italian citizenship. The mean age was 30, with about half in the 25-34 age category. The regions of origin were Asia, followed by Africa, with Pakistan and Nigeria the most represented countries. Forty-two percent had a middle or primary school education, and a similar proportion had a high school degree, with a small minority being students. A significant number (34%) reported having difficulties understanding Italian. About 40% of respondents lived outside the city.

Work characteristics are summarized in Table 2.

Our sample consisted of riders with limited experience, with a mean job duration of about years. Most were self-employed with a VAT number or employed under precarious contracts. One of the interviewees, a 17-year-old, reported working under a contract that was not in his name. All major active platforms in Milan were represented: 30% worked exclusively for Platform A, which employs autonomous or precarious contract workers and embraces a 'free login' type of organization. Riders working for Platform B, a more classical shift-based organization that extensively uses permanent contracts, comprise 23% of the sample. Riders working for Platform C, which employs a shift-based work organization, precarious or autonomous contracts, and a reward system that enables them to pick new shifts, represented 12% of the total.

Additionally, 25% of respondents worked for more than one company (multi-account workers). One of the riders reported working without a proper contract through an intermediary. Most respondents owned their working vehicle, mainly e-bikes or traditional bicycles, and used backpacks. Only 13% of riders sought trade union support; the main reason for not seeking support was a lack of knowledge. Regarding work schedules, about 23% worked more than 8 hours per day, and 44% reported working seven days a week.

Table 1. Personal characteristics of the interviewed riders. Data are reported as count (%).

Variable	Categories	No. (%)
Sample size	**Total**	240 (100)
Sex	Male	233 (97)
	Female	3 (1)
Age (years)	<25	47 (20)
	25-29	69 (29)
	30-34	46 (19)
	>=35	69 (29)
	Overall mean±sd	30 ± 7
Origin country/continent	Italy	39 (16)
	Europe (other than Italy)	3 (1)
	Asia	118 (49)
	Africa	69 (29)
	Central-South America	7 (3)
Italian citizenship	Yes	53 (22)
	No	184 (77)
Italian comprehension	Well	73 (30)
	Quite well	83 (35)
	With many difficulties	52 (22)
	Do not understand	29 (12)
Student	Yes	30 (13)
	No	207 (86)
Education	Degree/master's degree or higher	28 (12)
	High school	97 (40)
	Middle school or primary school	102 (43)
	Other	3 (1)
Residence	Milan	142 (59)
	Province of Milan	60 (25)
	Other areas of the region	36 (15)

N.B.: N.A.s not reported but covered by % computation.

Riders typically traveled more than 20 km per day and delivered between 5 and 15 orders daily.

3.2. Determinants of Overworking

Table 3 reports the probability of working seven days per week and more than eight hours per day in relation to various variables of interest.

The probability of overworking was higher for autonomous workers and riders without Italian citizenship, increasing with age. It was also higher for those employed by platforms with non-traditional shift-work organizations (Platforms A and C) or those working for multiple platforms (multi-account). In contrast, students had a lower risk of overworking. Multivariate regression analysis (S4) confirms that platform type, citizenship, and contract type were associated with overworking. Due to the lower impact of Platform B on overworking, a sensitivity analysis was performed by

Table 2. Work-related information. Data are reported as count (%).

Variables	Categories	No. (%)
Job duration	<12 months	47 (20)
	12-36 months	151 (63)
	>36 months	37 (15)
	Months (mean±sd)	26 ± 20
Type of contract	Permanent	88 (37)
	Autonomous (VAT)	98 (41)
	Precarious	36 (15)
Platform	Platform A	71 (30)
	Platform B	56 (23)
	Platform C	28 (12)
	Multi-account	60 (25)
	Others	17 (7)
Number of active accounts for different platforms (multi-account)	1	172 (72)
	2	45 (19)
	> 2	14 (6)
Ownership of the vehicle	Rider	205 (85)
	Platform	20 (8)
	Other	4 (2)
Working vehicle	E-bike	111 (46)
	Traditional bicycle	96 (40)
	Moped/motorcycle	21 (9)
	Other	6 (2)
Use of backpack	No	35 (15)
	Yes	117 (49)
Use of a smartphone sport	No	32 (13)
	Yes	121 (50)
Riders who have asked for support from trade unions	Platform A	6 (19)
	Platform B	15 (47)
	Platform C	4 (13)
	Multi-account	5 (16)
	Others	1 (3)
Reasons for not having asked for trade unions' support	Never heard about them	93 (39)
	NeveI never taught about/Never needed	55 (23)
	I talk with colleagues and don't trust them	35 (15)
	I ask the company	3 (1)
Working hours per day	<3	10 (4)
	3-4	47 (20)
	5-6	60 (25)
	7-8	61 (25)
	>8	56 (23)

Table 2 (*Continued*)

Variables	Categories	No. (%)
Working day per week	<3	8 (3)
	3-4	32 (13)
	5-6	90 (38)
	7	105 (44)
Deliveries per day	<5	7 (3)
	5-10	90 (38)
	11-15	77 (32)
	16-20	41 (17)
	>20	19 (8)
Km per day	>20	147 (61)
	16-20	42 (18)
	11-15	22 (9)
	5-10	17 (7)
	<5	3 (1)

N.B.: N.A.s not reported but covered by % computation.

excluding the platform from the dataset. The results remained consistent, showing no significant differences compared to the full dataset.

3.3. Occupational Safety and Health Information

Table 4 shows the primary information on OSH, including road accidents, assaults, and possible work-related issues.

Thirty-nine percent of riders reported at least one road accident in the past year, with e-bike riders being the most affected. Accidents mainly occurred during the evening (5-7 pm). Common accidents included collisions with vehicles and falls due to wet cobblestones and poor road conditions. Most victims reported health consequences, primarily back and knee injuries, with 35% requiring hospital assistance. Moreover, 29 riders reported physical assaults, and 67 reported verbal assaults. Over half of the riders suffered from work-related health issues, mainly musculoskeletal disorders (MSDs) and fatigue.

3.4. Determinants of Road Accidents and Work-Related Health Issues

Table 5 shows the probability of being a victim of a road accident and suffering from back pain and fatigue in relation to selected variables.

The probability of road accidents was higher for e-bike riders and those experiencing fatigue, which increased with traveled distance and number of deliveries. This probability was lower for students and precarious workers. Multivariate regression analysis (S6) confirms strong associations with vehicle type and fatigue and suggests likely associations with backpack use and the number of deliveries. Regarding work-related health issues, back pain probability increases with age, job duration, daily traveled distance, backpack, and e-bike use. This probability was lower among those with lower education and autonomous or precarious riders working for platforms A and C or using multiple accounts. Similar trends were observed when considering fatigue, except for vehicle type influence. Multivariable logistic regression analysis confirms important roles for backpack use and daily travel distance, with a suggestive association for vehicle type (S8).

4. Discussion

4.1. Safety Concerns for an Evolving and Vulnerable Workforce

Our results shed further light on the vulnerability of individuals working as riders within the digital food delivery sector. Our sample was predominantly

Table 3. Crude odds ratio (OR) of the occurrence of overworking. The number (%) of cases belonging to each subgroup and the total number of respondents (Total) are reported, along with OR estimates and 95% Confidence Intervals (CI).

		Days/week = 7			Hours/day > 8		
Variables		**n. (%)**	**Total**	**OR (95% CI)**	**n. (%)**	**Total**	**OR (95% CI)**
Age (yr)	<25	15 (32)	47	1.00 (Ref)	6 (13)	45	1.00 (Ref)
	25-29	33 (50)	66	2.13 (0.99-4.74)	14 (21)	66	1.79 (0.66-5.45)
	30-34	23 (50)	46	2.13 (0.93-5.03)	11 (24)	45	2.10 (0.72-6.63)
	>=35	34 (49)	69	2.07 (0.97-4.57)	25 (36)	69	3.79 (1.49-11.05)
Citizenship (Italian)	Yes	8 (16)	50	1.00 (Ref)	6 (12)	50	1.00 (Ref)
	No	96 (52)	184	5.73 (2.67-13.77)	50 (38)	133	2.76 (1.18-7.56)
Student	Yes	3 (10)	30	0.11 (0.03-0.33)	1 (3)	30	0.09 (0.01-0.45)
	No	101 (50)	204	1.00 (Ref)	55 (27)	203	1.00 (Ref)
Education	Degree/higher	12 (43)	28	1.00 (Ref)	8 (29)	28	1.00 (Ref)
	High school	39 (42)	94	0.95 (0.40-2.26)	20 (21)	94	0.68 (0.26-1.83)
	Middle school or lower	51 (50)	102	1.33 (0.58-3.2)	26 (26)	101	0.87 (0.35-2.30)
Job duration (yr)	<1	24 (51)	47	1.00 (Ref)	14 (30)	47	1.00 (Ref)
	1-3	66 (45)	148	0.77 (0.40-1.49)	34 (23)	148	0.70 (0.34-1.49)
	>3	14 (38)	37	0.58 (0.24-1.39)	7 (19)	36	0.57 (0.19-1.57)
Type of Contract	Permanent	23 (26)	88	1.00 (Ref)	14 (16)	88	1.00 (Ref)
	Autonomous	65 (66)	98	5.57 (2.99-10.66)	37 (38)	97	3.26 (1.64-6.76)
	Precarious	10 (28)	36	1.09 (0.44-2.56)	2 (6)	36	0.31 (0.05-1.20)
Platform	Platform A	51 (72)	71	68.85 (18.97-445.91)	29 (41)	70	19.10 (5.33-122.45)
	Platform B	2 (4)	56	1.00 (Ref)	2 (4)	56	1.00 (Ref)
	Platform C	13 (46)	28	23.40 (5.68-160.74)	4 (14)	28	4.5 (0.82-34.1)
	Multi-account	33 (52)	63	29.70 (8.24-191.24)	19 (28)	67	10.80 (2.91-70.27)

composed of a foreign workforce without citizenship, working under precarious or autonomous contracts, and possessing limited knowledge of Italian. These findings are consistent with the literature, mainly focusing on the urban gig economy [21]. Cultural and language barriers represent the most pressing issues as they contribute significantly to health and safety risks and social vulnerabilities [24]. Riders with limited knowledge of the local language are more prone to discrimination, hostility, and exploitation, often unaware of their rights and the possibility of receiving union support [22]. These considerations align with our results, which indicate a high prevalence of overwork and a lower likelihood of reporting work-related health issues among riders with precarious contracts and without union support.

Additionally, a rider working with a contract not in his name confirms that non-transparent intermediation practices still occur in the Italian labor market, further exacerbating job insecurity and exploitation. Nonetheless, the widespread ownership of working vehicles, including motorcycles and e-bikes, indicates a high level of rider commitment and investment, suggesting a shift towards long-term employment rather than transient gig work. Compared to Fasano & Natale's 2019 survey in Milan, our study involved an older, ethnically different

Table 4. Occupational safety and health information of the 240 interviewed riders. Data are reported as count (%).

Variables	Categories	No. (%)
	Total	91 (38)
Riders reporting road accidents	E-bicycle	54 (59)
	Bicycle	27 (30)
	Moped/motorcycle	8 (9)
	Evening (17-19)	36 (40)
	Lunchtime (12-15)	21 (23)
	Dinner time (19-22)	17 (19)
	Collision with other vehicles	29 (32)
	Fall by wet cobblestones/road	26 (29)
	Road conditions (e.g., road potholes/holes)	25 (28)
Sequelae after road accidents	Total	81 (34)
	Knees/pelvis/legs or feet pain	39 (48)
	Back pain	28 (35)
	Wrists or arms or hand pain	25 (31)
Hospital assistance after road accidents	Total	32 (13)
	Collision with other vehicles	17 (53)
	Fall by wet cobblestones/road	11 (34)
	Road conditions (e.g., road potholes/holes)	6 (19)
Physical assault	Total	29 (12)
	Fearing for health	14 (48)
Verbal assault	Total	67 (28)
	Fearing for health	12 (18)
	Total	150 (63)
Possible work-related health issues	Back pain	89 (59)
	Fatigue	73 (49)
	Shoulders/neck pain	48 (32)

population. In particular, fewer riders were under 25 years old (20% vs. 57%), and the Asian component increased from 15% to 49% [25]. This reflects recent immigration trends [32] and indicates the significant turnover of an evolving workforce. African workers were more reluctant to be interviewed, possibly leading to their underrepresentation.

4.2. Health and Safety Consequences of Algorithmic Management

Researchers have focused on the algorithm-rider relation in the last years, arguing that making riders free to connect/disconnect from the system does not go together with more control over the labor process [13] but leads them to work overload and burnout [14]. In our study, we observed a similar trend with riders employed with permanent contracts and in traditional shift-work organizations not experiencing overwork. At the same time, those working in a free-login modality were more exposed. Nevertheless, riders employed by Platform C were also more likely to overwork despite using a shift-work organization. A possible explanation is that these riders are employed as autonomous workers within a national collective agreement framework that does

Table 5. Crude odds ratio (OR) of the occurrence of road accidents, back pain, and fatigue. The number (%) of cases belonging to each subgroup and the total number of respondents (Total) are reported, as well as OR and 95% Confidence Intervals (CI).

		Road Accidents			Health issues					
					Back pain			Fatigue		
Variables		**n. (%)**	**Tot**	**OR (95% CI)**	**n. (%)**	**Total**	**OR (95% CI)**	**n. (%)**	**Total**	**OR (95% CI)**
Age (yr)	<=25	16 (35)	46	1.00 (Ref)	11 (23)	47	1.00 (Ref)	9 (19)	47	1.00 (Ref)
	26-30	24 (39)	62	1.18 (0.54-2.65)	25 (25)	69	1.86 (0.82-4.41)	27 (39)	69	2.71 (1.17-6.78)
	31-35	22 (49)	45	1.79 (0.78-4.22)	22 (48)	46	3.00 (1.25-7.51)	18 (39)	46	2.71 (1.09-7.18)
	>35	28 (47)	60	1.64 (0.75-3.67)	27 (39)	69	2.10 (0.93-4.97)	18 (26)	69	1.49 (0.62-3.81)
Citizenship (Italian)	Yes	19 (39)	49	1.00 (Ref)	21 (40)	53	1.00 (Ref)	21 (40)	53	1.00 (Ref)
	No	72 (43)	166	1.21 (0.63-2.35)	68 (37)	184	0.89 (0.48-1.69)	52 (28)	184	0.60 (0.32-1.15)
Student	Yes	11 (39)	28	0.37 (0.37-1.93)	12 (40)	30	1.13 (0.50-2.44)	8 (27)	30	0.79 (0.32-1.81)
	No	80 (43)	187	1.00 (Ref)	77 (37)	207	1.00 (Ref)	65 (31)	207	1.00 (Ref)
Degrees	Higher	11 (44)	25	1.00 (Ref)	15 (54)	28	1.00 (Ref)	10 (36)	28	1.00 (Ref)
	High school	37 (44)	84	1.00 (0.41-2.50	35 (36)	97	0.49 (0.21-1.14)	30 (31)	97	0.81 (0.34-2.01)
	Middle or lower	39 (40)	98	0.84 (0.35-2.08)	33 (32)	102	0.41 (0.17-0.97)	29 (28)	102	0.72 (0.30-1.78)
Job duration (yr)	<1	-	-	-	-	47	1.00 (Ref)	12 (26)	47	1.00 (Ref)
	1-3	-	-	-	-	151	1.47 (0.74-3.05)	46 (31)	151	1.28 (0.62-2.77)
	>3	-	-	-	-	37	1.80 (0.73-4.48)	13 (35)	37	1.58 (0.62-4.10)
Contract	Permanent	36 (48)	75	1.00 (Ref)	39 (44)	88	1.00 (Ref)	32 (36)	88	1.00 (Ref)
	Autonomous	41 (44)	94	0.84 (0.45-1.54)	38 (39)	98	0.80 (0.44-1.43)	29 (30)	98	0.74 (0.40-1.36)
	Precarious	11 (31)	35	0.50 (0.21-1.14)	8 (21)	39	0.32 (0.13-0.76)	8 (21)	39	0.45 (0.18-1.06)’
Working hours	<5	17 (33)	51	1.00 (Ref)	28 (49)	57	1.00 (Ref)	17 (30)	57	1.00 (Ref)
	5-8	56 (48)	117	1.84 (0.93-3.71)	42 (35)	121	0.55 (0.29-1.04)	46 (38)	121	1.44 (0.74-2.89)
	>8	18 (38)	48	1.20 (0.53-2.75)	19 (34)	56	0.53 (0.25-1.13)	10 (18)	56	0.51 (0.20-1.23)
Working days	<5	16 (41)	39	1.00 (Ref)	13 (33)	40	1.00 (Ref)	12 (30)	40	1.00 (Ref)
	5-6	32 (39)	82	0.92 (0.42-2.02)	39 (43)	90	1.59 (0.74-3.55)	35 (39)	90	1.48 (0.68-3.38)
	7	43 (45)	95	1.19 (0.56-2.56)	37 (35)	105	1.13 (0.53-2.50)	26 (25)	105	0.77 (0.35-1.76)
Daily traveled distance (km)	<15	10 (26)	38	1.00 (Ref)	9 (21)	42	1.00 (Ref)	9 (21.4)	42	1.00 (Ref)
	15-20	17 (41)	42	1.90 (0.75-5.05)	16 (36)	44	2.26 (0.87-6.12)	12 (28.6)	42	1.47 (0.54-4.06)
	>20	62 (47)	132	2.48 (1.15-5.74)	61 (42)	147	2.60 (1.20-6.14)	50 (34.0)	147	1.89 (0.87-4.48)

Table 5 (*Continued*)

					Health issues					
		Road Accidents			Back pain			Fatigue		
Variables		**n. (%)**	**Tot**	**OR (95% CI)**	**n. (%)**	**Total**	**OR (95% CI)**	**n. (%)**	**Total**	**OR (95% CI)**
Type of vehicle	Normal bicycle	27 (32)	84	1.00 (Ref)	32 (33)	96	1.00 (Ref)	28 (29)	96	1.00 (Ref)
	E-bike	54 (51)	105	2.24 (1.24-4.10)	49 (44)	111	1.58 (0.90-2.80)	33 (30)	111	1.03 (0.56-1.88)
	Other	10 (37)	27	1.24 (0.49-3.04)	8 (30)	27	0.84 (0.32-2.08)	12 (44)	27	1.94 (0.80-4.68)
Number of deliveries	<11	32 (36)	90	1.00 (Ref)	40 (41)	97	1.00 (Ref)	28 (29)	97	1.00 (Ref)
	11-15	30 (42)	72	1.29 (0.68-2.45)	30 (39)	77	0.91 (0.49-1.67)	27 (35)	77	1.33 (0.70-2.53)
	>15	28 (53)	53	2.03 (1.02-4.08)	18 (30)	60	0.61 (0.30-1.20)	17 (28)	60	0.97 (0.47-1.98)
Platform	Platform A	27 (43)	63	0.85 (0.47-2.14)	30 (42)	71	0.59 (0.29-1.19)	14 (20)	71	0.33 (0.15-0.71)
	Platform B	21 (43)	49	1.00 (Ref)	31 (55.4)	56	1.00 (Ref)	24 (42.9)	56	1.00 (Ref)
	Platform C	15 (56)	27	1.67 (0.65-4.36)	5 (18)	28	0.18 (0.05-0.50)	8 (29)	28	0.53 (0.19-1.38)
	Multi-account	25 (39)	64	0.85 (0.40-1.83)	20 (29)	73	0.38 (0.18-0.79)	21 (30)	70	0.57 (0.27-1.19)
Use of backpack	No	17 (33)	52	1.00 (Ref)	16 (31)	52	1.00 (Ref)	9 (26)	35	1.00 (Ref)
	Yes	44 (46)	96	1.74 (0.87-3.58)	51 (51)	100	2.34 (1.17-4.84)	54 (46)	118	2.48 (1.10-6.01)
Experiencing fatigue	No	50 (34.7)	144	1.00 (Ref)	-	-	-	-	-	-
	Yes	41 (56.9)	72	2.49 (1.40-4.47	-	-	-	-	-	-

not include time restrictions or fixed working hours. Besides, Platform C embraces the so-called "badge system" [14], which aims at ranking workers according to their performances (e.g., likelihood to accept shifts, canceling or not going to shifts, etc.), precluding or favoring the opportunity to participate to the most profitable shifts. This appraisal system may reduce workers' autonomy, leading them to pick shifts regardless of their schedules, thereby increasing the risk of overwork and the likelihood of risky behaviors [33-34]. Still, work organization remains a crucial factor to consider when analyzing OSH in the gig economy and also when referring to road safety. The intensive working schedules reported by riders, with almost 44% working seven days a week (23% for more than 8 hours/day) and fatigue among the most reported occupational health disorders, generate concerns, especially in light of the higher probability of accidents emphasized by both our findings and the recent literature [17, 35-37].

4.3. Underreported Issues: Road Safety Challenges

We reported a high prevalence of road accidents (~40%), consistent with the literature [15-17, 19], though not reflected in institutional records. For instance, the 2021 dataset from the National Institute for Statistical Analysis (ISTAT) shows only ten road accidents involving two-wheel riders during work in Milan, while the National Institute for Insurance against Accidents at Work (INAIL) reports 84 injuries for the entire Lombardy region, where Milan is located. Underreporting of occupational accidents is a known issue linked with cultural barriers, job precarity, and social vulnerability [38, 39]. Our study found that the leading causes of road accidents were poor road conditions (e.g., holes and potholes), inattention, inadequate driving skills (e.g., the ability to ride in wet conditions), and possibly heavy and destabilizing loads on precarious vehicles. However, 53% of riders cited collisions with other vehicles as the primary cause when hospital visits were required, indicating the most significant health risk.

Additionally, 24% of riders reported collisions with opened vehicle doors, a common hazard for urban cyclists [40]. These findings align with the literature. For instance, Dennerlein and Meeker (2002) found high crash injury rates in 113 urban bicycle couriers in Boston [15]. Heyer et al. (2015) reported that 21.9% of commercial bicycle rider accidents in New York involved open car doors [16]. Christie & Ward (2019) found that 80% of bicycle riders in their study reported road accidents, often due to fatigue and violation of speed limits due to rush [17]. Recent studies highlight behaviors and external factors influencing rider risk. Perkio (2023) found that financial pressure led delivery workers in Sweden to take risks [22]. Bonifacio (2022) identified contradictions between algorithmic management, piecework payment, and safety behaviors among riders in Milan [41]. Our results also show a link between the number of daily deliveries, the distance traveled, and the likelihood of road accidents, with higher numbers increasing the risk. In our study, many e-bikes were traditional bicycles modified with electric batteries (likely failing to meet safety standards), increasing the risks for excessive speed, weight, inadequate braking systems, and instability [16]. The widespread ownership of vehicles (85%) further increases safety risks, as maintenance responsibility falls on riders; in addition, financial strain may discourage vehicle maintenance, exacerbating health and safety risks [42].

4.4. Violence and Physical Strain: Critical Issues Not to Be Underestimated

Violence and aggression at work during delivery have been reported in the literature. For instance, Dennerlein & Meker (2002) reported that 1% of work-related injuries were due to on-road assaults/violence [15]. Lachapelle et al. (2021) noted road rage and harassment among many of the 35 interviewed commercial cyclists, while Perkio et al. (2023) reported experiences of violence and aggression in different situations, such as attempted theft of vehicles [18, 22]. Given the significant prevalence of both physical (12%) and verbal (28%) assaults we found in our investigation, we recommend placing more emphasis on this issue. Working as a rider exposes individuals not only to safety and psychosocial risks but also to physical strain.

For example, Li et al. (2022) investigated musculoskeletal disorders (MSD) among 657 bicycle riders working in Shanghai (China), finding a high prevalence (55%) of MSD, particularly associated with shoulder, neck, knee,e, and forearm, with longer job duration increasing symptoms likelihood [20]. These results align with our findings, where using backpacks and job duration are possible determinants of MSD.

4.5. Possible Scenarios to Improve Working Conditions

Based on our findings, intervention should adopt a multi-level approach, including policy changes, technological innovations, and work, as well as place culture shifts involving various stakeholders such as employers, communities, and city councils. Empowering riders with knowledge of their rights and union support will enable them to advocate for safer and more supportive work environments. Policymakers should ensure that algorithmic management processes are transparent and incorporate parameters to reduce OSH risks and limit physical and mental strain [43-44]. These factors should be monitored by an effective worker health surveillance system and prevented through improvements in the working environment, safety culture, and technologies. For instance, creating rider-friendly urban environments, such as providing hubs for rest and essential services, can enhance well-being, alleviate mental and physical strain, and promote social interactions. The Vision Zero plan embraced by the European Union in 2021, which promotes safer urban environments and effective speed and traffic control policies [45], can significantly reduce road accidents for food delivery riders.

Additionally, mandatory safety training and ergonomic guidelines for load management, including correctly using well-designed backpacks, can alleviate daily physical strain. Moreover, the high prevalence (40%) of riders commuting from outside the city can be seen as an alarm sign for social inequality, such as the lack of affordable housing options and discrimination in housing markets. Housing policies that promote inclusivity for a broad spectrum of socio-economic groups can improve the living conditions and well-being of migrant workers, including food delivery riders. Finally, establishing a reporting system for violence and harassment, along with accessible support services, can address critical psychosocial risks.

4.6. Study Limitations and Strengths

While this study provides valuable insights into the OSH of food delivery riders, it is essential to acknowledge its methodological limitations. In particular, the findings may be of limited generalizability due to the local scale and the selection bias, as recruitment relied on casual involvement and voluntary participation. Moreover, for health outcomes, the survey is subject to self-report bias, and the cross-sectional design allows us to find associations but limits the possibility of establishing a causal link between determinants and outcomes. These factors highlight the need for experimental studies and objective measures in future research. Despite these limitations, the study's strengths lie in its empirical results, which cover a broad range of OSH topics, offering a vast understanding of the phenomenon. Additionally, although not representative of the entire workforce, the relevant number of subjects employed by different platforms and directly recruited in the field without employer mediation likely provided a deeper and more genuine understanding of the issues faced by food delivery riders.

5. Conclusion

Our study reveals that food delivery riders in Milan, predominantly foreign and employed under precarious conditions, face significant vulnerabilities, including high rates of overwork, road accidents, and health issues like musculoskeletal disorders and fatigue. The findings, aligned with recent literature, emphasize the need for improved regulatory measures and support systems to enhance rider safety and working conditions. Integrating decent work conditions and social protection principles from the 2030 Agenda for Sustainable Development [46] into public policies and platform practices will foster a safer and more supportive working environment for riders.

Supplementary Materials: The following are available online: Supplemental material S1-S8.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of the University of Milan (approval n. 42/22).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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SUPPLEMENTARY MATERIAL

Supplementary Material

S1. Questionnaire Evaluation Results

The evaluation of the questionnaire was conducted following Lynn et al., 1987 and Politt et al., 2006 and 2007. To this end, 8 evaluators were involved in the evaluation process. The expert panel was made up by health and safety professionals (occupational physicians, technicians from health and safety authority), labour law professionals working for the Municipality of Milan, and academic researchers operating in the occupational health and safety field. Experts were asked to rate the relevance and clarity of each item, and to suggest modifications. For each item, content Validity Index (I-CVI) was determined as the proportion of score 3 or 4 on the total number of scores. Finally, to evaluate the questionnaire as a whole, the "Scale-Content Validity Index" (S-CVI/Ave) was calculated as the average of all the computed I-CVIs. The whole document was considered of sufficient validity and clarity with S-CVI/Ave of 0.90 or higher. The evaluation of the questionnaire for both relevance and clarity was successfully completed with S-CVI/Ave score of 0.945 and 0.909 respectively if considering validity and clarity.

S2. Final Version Questionnaire

The final questionnaire is the outcome of both the evaluation process of the first draft and supplemental considerations and suggestions proposed by the same evaluators as well as by the workers we involved in the final review of the draft. The final version of the questionnaire is reported below. The S, O and M letters refer to Single choice, Open or Multiple choice type of answer.

Personal information items		**Answers**	
1	Do you understand Italian? (e.g. when you talk to an Italian customer, can you understand everything he/she says/asks you?)	Well Quite well With many difficulties I do not understand	S
2	Where were you born (Country of birth, e.g. Italy):	____	O
3	How many YEARS have you been in Italy:	____	O
4	Do you have the Italian citizenship?	Yes No	S
5	Sex	Male Female Intersex I prefer not to answer	S
6	How old are you (in years)?	____	O
7	Are you a student?	Yes No	S
8	What degree do you have?	Degree/master degree or upper High school Middle school or primary school Other:_____	S
9	Where do you live?	XXX XXX province Other areas in XXX	S
General information about work		**Answers**	
10	How many YEARS have you worked as a rider?	____	O
11	How many MONTHS have you worked as a rider?	____	O
12	How many platforms/companies are you currently working for?	one two more than two	S
13	Which platforms/companies do you work for?	Deliveroo Glovo Just Eat Uber eats My menù Other:_____	M
14	What kind of contract do you have?	With VAT number Permanent contract Occasional service Continuous collaboration (Co.co.co) I do not know Other:_____	S
15	What is the payment method used by your company?	Travelled km By hours Only number of deliveries Number of deliveries + travelled km	

General information about work		**Answers**	
16	How many hours a day do you work?	1-2 hours 3-4 hours 5-6 hours 7-8 hours >8 hours	S
17	How many days do you usually work a week?	1-2 days 3-4 days 5-6 days 7 days	S
18	How many deliveries do you usually make a day?	Less than 5 5 to 10 11 to 15 16-20 More than 20	S
19	How many kilometers do you usually make per day?	Less than 5 5 to 10 11 to 15 16-20 More than 20	S
20	Have you ever called for support to the labor union for work-related issues?	Yes No	S
21	If NO, why?	I've never heard of such things I never thought about it I don't trust them I ask other associations I talk with my colleagues Other:_____	S
Questions about safety		**Answers**	
22	Do you think your job is dangerous for your health/safety?	Absolutely no A little Enough Very dangerous	M
23	What type of transport means do you use most often?	Traditional bicycle E-bike Motor scooter/moped Electric scooter/kick-scooter Other:_____	
24	The means of transportation you use to work:	Is yours Is of the company Other:_____	S
25	Which of the following devices do you use during work?	Helmet Reflective vest Other reflective items Front lights Back lights Bell/horn/trumpet Back brace Gloves Other:_____	M

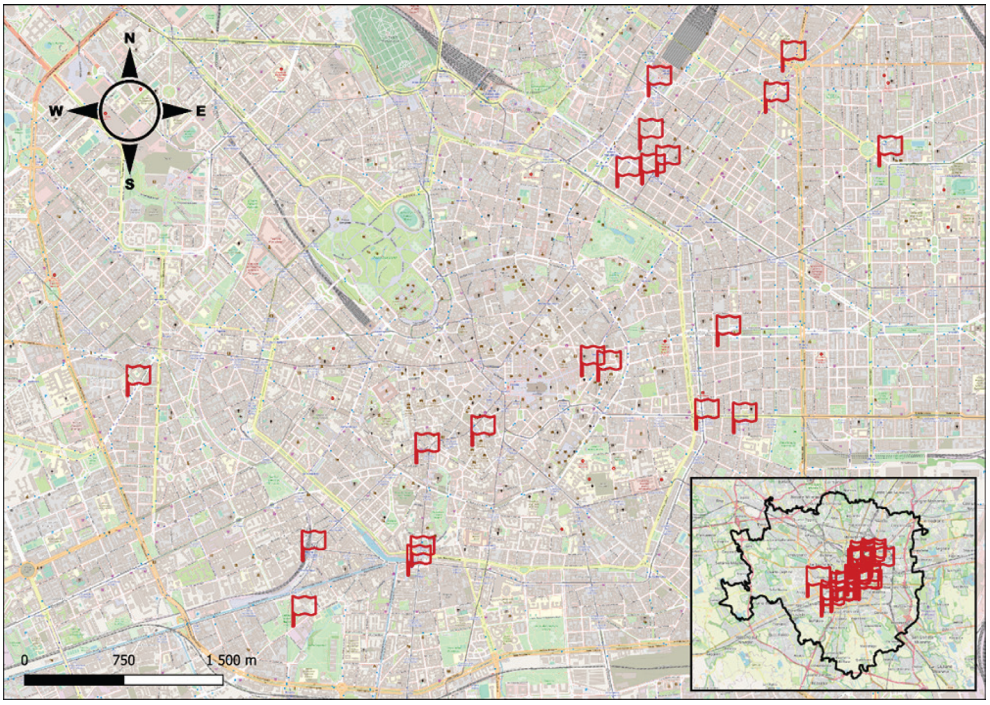
Questions about safety		**Answers**	
26	Have you taken one or more safety training courses?	Yes No	
27	Would you be interested to attend the following free courses organized by the City of Milan: Italian language Road and work safety	Yes No	S
28	What other topics would interested in for these courses?	_____	O
29	Which of the following concerns worries you the most while working? (please indicate a maximum of 5 options)	Traffic Your means of transport Using your mobile phone Air pollution Fatigue Road conditions (e.g: road potholes/holes) Cobblestones Tram tracks Number of deliveries The many hours in the saddle Being always available/ contactable The number of working hours Going around with the money of the deliveries Car not parked properly (e.g double parking) The speed of other vehicles Lack of bicycle paths/lanes The weight of the backpack None of these Other:_____	M

Questions about road accidents		**Answers**	
30	Over the past year, how many accidents have you had during deliveries?	_____	O
31	At what time did you have these accidents? morning (7-12): lunch time (12-15): afternoon (15-17): evening (17-19): night (22-7):	Yes No	S
32	How many times did you have to go to the hospital because of such accidents?	_____	O
33	Over the last year, which of the following types of accidents have you had?	Collision with the door of a parked vehicle Collision with pedestrian Fall to avoid pedestrian Crash/fall due to road conditions (e.g road potholes/holes)	

Questions about road accidents		Answers	
		Collision with car/truck Collision with motor scooter/moped Fall to avoid other vehicle Fall/collision due to inattention Fall/crash due to the use of mobile phone Fall caused by tram tracks Fall caused by wet cobblestones/ road Other:_____	M
34	Following accidents during deliveries, which consequences did you have:	Back pain/issues Neck or shoulder pain/issues Head or face pain/issues Wrists or arms or hand pain/ issues Knees or pelvis or legs or feet pain/issues Psychological issues (panic, depression, anxiety) Other:_____	M
Questions about assaults		**Answers**	
35	Over the past year, how many times have you been PHYSICALLY assaulted during work?	_____	O
36	What were the most frequent reasons for the PHYSICAL attacks you suffered? N.B: DO NOT provide information that may lead to the identification of yourself or others	Road issues (e.g.: a missed stop/ give-way sign) Theft of transported goods Theft of your vehicle Other:_____	M
37	Over the past year, how many times have you been assaulted VERBALLY during work?	_____	O
Questions about health		**Answers**	
38	Since you work as a rider, do you suffer from some of the following health issues?	Back pain/discomfort Arms or wrists or hands pain/ discomfort Neck or shoulder pain/ discomfort Knees pain/discomfort Persistent cough Inflammation of the throath Eye discomfort/inflammation Headache Fatigue Urinary/genital system issues Panic/depression or anxiety Other:_____	M

Supplementary items		**Answers**	
S1	Do you like your job?	A lot So and so A little I don't like it at all	S
S2	Specify why: N.B: DO NOT provide information that may lead to the identification of yourself or others	_____	O
S3	Are you going to change job in the next few months?	Yes No	S
S4	Specify why you intend to change jobs N.B: DO NOT provide information that may lead to the identification of yourself or others	_____	O
S5	Can you freely decide your working hours?	Yes, always Only a few times Rarely Never	S
S6	While working: I wear a backpack on my shoulders I load the backpack on the carrier	Yes, always Only a few times Rarely Never	S
S7	How often is your working vehicle checked/serviced?	1-3 months 4-6 months 7-12 months > 13 months Never I do not know	S
S8	During one or more of the reported road accidents, have you ever been afraid for your health/have you thought about dying?	Yes No I had no accident	S
S9	During one or more PHYSICAL ASSAULTS you suffered, have you ever been afraid for your health/ have you thought about dying?	Yes No I did not suffer any assault	S
S10	During one or more VERBAL ASSAULTS, have you ever been afraid for your health/have you thought about dying?	Yes No I did not suffer any assault	S
S11	Since you've been a rider, has your health deteriorated?	Not at all A little So and so A lot	S

S3. Map of XXX and Riders' Meeting Points, Where the Recruitment of Volunteers Was Performed. These Points Include the Following:



S4. Multivariate Logistic Regression for Overworking

In Models A, B, and C, we investigated the association between the platform, citizenship, and contract with overworking outcomes. All models were adjusted for education, age and student status of riders.

			Days/week = 7	Hours/day > 8
Variables			**CI95%**	**CI95%**
Model A	Platform	Platform B	1.00 (reference)	1.00 (reference)
		Platform C	20.30 (4.03-102.24)	4.64 (0.76-28.48)
		Platform A	67.91 (14.74-312.89)	19.24 (4.23-87.63)
		Multi-account	30.39 (6.58-140.39)	11.79 (2.50-55.52)
Model B	Citizenship	Yes	1.00 (reference)	1.00 (reference)
		No	4.25 (1.83-9.87)	2.23 (0.85-5.83)
Model C	Type of contract	Permanent	1.00 (reference)	1.00 (reference)
		Autonomous	5.70 (2.80-11.63)	3.69 (1.69-8.08)
		Precarious	1.40 (0.51-3.80)	0.40 (0.08-1.99)

S5. Road Accidents Information, Riders Could Give More than One Type of Answer

Sample size		**240**
Riders reporting road accidents, n (%)		91 (38)
Riders reporting road accidents by time, n (%)	evening (17-19)	36 (40)
	lunch time (12-15)	21 (23)
	dinner time (19-22)	17 (19)
	night (22-7)	14 (15)
	afternoon (15-17)	11 (12)
	morning (7-12)	9 (10)
Riders reporting road accidents by causes, n (%)	Fall by wet cobblestones/road	26 (29)
	Road conditions (e.g: road potholes/holes)	25 (27)
	Collision with car/truck	22 (24)
	Fall caused by tram tracks	13 (14)
	Collision with the door of a parked vehicle	12 (13)
	Fall to avoid other vehicle	8 (9)
	Fall to avoid pedestrian	7 (8)
	Fall/collision due to inattention	7 (8)
	Collision with motor scooter/moped	7 (8)
	Collision with pedestrian	3 (3)
	Other	3 (3)
	Fall/crash due to the use of mobile phone	1 (1)
	Fall down the stairs	1 (1)
Riders reporting health consequences after accidents, n (%)		81 (34)
Riders reporting health consequences after accidents by outcome, n (%)	Knees or pelvis or legs or feet pain/issues	39 (48)
	Back pain/issues	28 (35)
	Wrists or arms or hand pain/issues	25 (31)
	Neck or shoulder pain/issues	13 (16)
	Head or face pain/issues	6 (7)
	Psychological issues (panic, depression, anxiety)	4 (4)
	Chest	2 (2)
	None	1 (1)
Riders needing hospital assistance after road accidents, n(%)		32 (13)
Riders needing hospital assistance after road accidents by causes, n (%)	Collision with car/truck	13 (41)
	Road conditions (e.g: road potholes/holes)	11 (34)
	Fall by wet cobblestones/road	6 (19)
	Collision with motor scooter/moped	4 (13)
	Fall caused by tram tracks	3 (9)
	Fall/collision due to inattention	3 (9)
	Collision with the door of a parked vehicle	3 (9)
	Fall to avoid other vehicle	2 (6)
	Other	1 (3)
	Fall to avoid pedestrian	1 (3)
	Fall down the stairs	1 (3)
	Collision with pedestrian	1 (3)

S6. Multivariate Logistic Regression for Road Accidents

In Model A, B, C, D, and E we investigated the association between type of vehicle, fatigue, number of deliveries, the use of backpack, and the use of smartphone holder with road accidents. Model A was adjusted for age, student status, education, and type of contract. Model B was adjusted for age, student status, the type of contract, the type of vehicle, working hours/day, working day/week, the daily distance traveled, and the daily number of deliveries. Model C for age, student status, the type of contract, the type of vehicle, working hours/day, the daily distance traveled, and the type of contract. Models D was adjusted for education, age, and student status.

			Road accidents
Variables			**CI95%**
Model A	Type of vehicle	Normal bicycle	1.00 (reference)
		E-bike	2.23 (1.21-4.08)
		Other	1.27 (0.50-3.21)
Model B	Experiencing fatigue	No	1.00 (reference)
		Yes	2.71 (1.40-5.25)
Model C	Number of deliveries	<11	1.00 (reference)
		11-15	0.95 (0.0.45-1.98)
		>15	1.75 (0.76-4.02)
Model D	Use of backpack	no	1.00 (reference)
		yes	2.25 (0.90-5.67)

S7. Complete List of Type of Reported Health Issues

Sample size	**240**
Riders reporting health issues	150 (63)
Back	89 (59)
Fatigue	73 (49)
Neck/shoulders	48 (32)
Arms/wrists/hands	38 (59)
Headache	31 (59)
Knees	31 (59)
Eyes inflammation	16 (59)
Urinary/genital system	12 (59)
Panic/depression or anxiety	11 (59)
Persistent cough	9 (59)
Throath inflammation	6 (59)

S8. Multivariate Logistic Regression for Work-Related Health Issues

In Model A, B, C, D, and E we investigated the association between type of vehicle, the use of backpack, and travelled distance. Model A and B were adjusted for age, student status, education, and job duration. Model C was adjusted for age, student status, education, job duration, type of vehicle, working hours/day.

			Back pain	Fatigue
Variables			**CI95%**	**CI95%**
Model A	Type of vehicle	Normal bicycle	1.00 (reference)	1.00 (reference)
		E-bike	1.52 (0.83-2.77)	0.87 (0.46-1.65)
		Other	0.81 (0.30-2.18)	2.58 (0.99-6.69)
Model B	Use of backpack	No	1.00 (reference)	1.00 (reference)
		Yes	2.84 (1.31-6.16)	4.21 (1.54-11.54)
Model C	Daily traveled distance	<11	1.00 (reference)	1.00 (reference)
		11-15	2.55 (0.92-7.04)	1.42 (0.50-4.07)
		>15	2.91 (1.22-6.98)	2.86 (1.15-7.11)

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Psychometric Evaluation of a Measure of Evidence-Based Practice in Occupational Health

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Keywords: Questionnaire; Evidence-Based Practice; Evidence-Based Health Care

Abstract

Background: *Occupational Health Services (OHS) are obliged to follow the principles of evidence-based health care. However, there needs to be tools to measure this. Therefore, we developed and validated a questionnaire for evaluating OHS practitioners' attitudes, competence, and organisational support to perform evidence-based practice (EBP-OHS) following the JBI Model of Evidence-Based Healthcare.* **Methods:** *The questionnaire's content validity was assessed by 12 experts in the field. Then, an opportunity sample of 524 OHS practitioners completed the questionnaire. We examined the questionnaire's psychometric properties using exploratory factor analysis and subjected it to construct validity and reliability testing.* **Results:** *The content validity index of the chosen items was 0.78 or higher. Exploratory factor analysis revealed that the measure's construct validity was adequate (KMO 0.9). Principal component factor analysis supported a three-factor structure (all eigenvalues 1.3 or more), which explained 60.3 % of the total variance. Aligned with these three factors, the EBP-OHS consists of three domains: Organisational support (seven items), OHS practitioners' competence (six items) and OHS practitioners' attitudes (two items). The scale's reliability is good (Cronbach alpha 0.88).* **Conclusions:** *The EBP-OHS is a valid tool for measuring occupational health services' evidence-based practice and enabling the implementation of research into practice. It embodies the phases of evidence transfer and implementation described in the JBI Model of Evidence-Based Healthcare and translates them into concrete measurable activities in the OHS context.*

1. Introduction

Evidence-based healthcare, formulated by the Joanna Briggs Institute (JBI), consists of five phases: global health, evidence generation, synthesis, transfer, and implementation [1]. The JBI model of Evidence-Based Healthcare (EBHC) was developed within the field of nursing science to establish a shared vision and language for the people generating and for those implementing evidence into practice. Although the model was developed within the nursing field, it is nonetheless very relevant and applicable within all healthcare. In this JBI Model, evidence-based practice (EBP) occurs during the phase of evidence implementation. According to the model [2], evidence-based practice involves "…giving consideration to the best available evidence; the context in which the care is delivered; client preference; and the professional judgement of the health professional". At occupational health service (OHS) practices, evidence implementation means utilising information synthesised from

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research to inform decision-making involving workers and their health and safety. In addition to evidence-based practice and decision-making at the level of individual service users, OHS organisations also cater to enterprises as clients.

Only a few studies have focused on evidence-based practice and its provision in the occupational healthcare context specifically. Attitudes towards EBP have been recognised as positive [3–5]. Additionally, previous evidence has shown that providing evidence-based practice in the occupational health context requires strong organisational and management support, both of which have been typically lacking [3]. Managers should be able to create a culture that supports EBP and enables adequate competence, support, and resources for employees [6]. To achieve the required organisational and managerial support in OHS, there is a need to evaluate the present state of evidence-based practice and recognise targets for development.

The range of published instruments for measuring evidence-based practice in healthcare has been thoroughly mapped with two systematic reviews [7, 8]. They both provided detailed descriptions only of the instruments their authors considered to be of the highest quality. Both reviews concluded that most researchers used the Fresno scale [9]. The Fresno scale tests the respondent's ability to frame a research question, search for evidence to answer it, understand the hierarchy of evidence, interpret its magnitude and internal and external validity, and grasp basic statistical and methodological concepts [10]. The tool effectively evaluates how well the respondents can obtain and interpret scientific evidence.

On the other hand, measuring attitudes towards EBP is a crucial feature of a few other scales, for example, the EBPQ [11] and the Quick EBP-VIK [12], both of which have been developed to be used only with nurses. Similarly, the scale developed by Heselmans et al. [4] focuses on Flemish occupational health physicians' attitudes toward evidence-based occupational health and clinical practice guidelines. In other words, previous tools focus either 1) on the ability to obtain and understand scientific evidence or 2) on healthcare workers with particular job titles. Moreover, previous tools are not built on an operationalised practical understanding of EBHC, nor do they gauge the support respondents receive from their employers. This study aimed to develop and psychometrically test a new questionnaire for evaluating OHS practitioners' attitudes, competence, and organisational support to perform evidence-based practice (EBP-OHS). The questionnaire is built on a sound theoretical footing provided by the JBI Model of Evidence-Based Healthcare, specifically its phases of evidence transfer and implementation at an organisational level. It also applies equally to nurses and physicians and acknowledges the specific requirements of the occupational healthcare arena.

2. Methods

The study included three phases of questionnaire development: item generation (phase 1), expert evaluation (phase 2) and psychometric testing (phase 3).

In phase 1, we developed the items of the questionnaire based on earlier research, and the instrument's development proceeded inductively [13]. Relevant earlier work consisted of a study conducted by the Finnish Nursing Research Foundation in which they first developed and used a questionnaire to assess EBP in primary care in Finland [14] and another study that developed further an earlier questionnaire [4] focusing on attitudes towards evidence-based practice in OHS. We evaluated the contents of these two tools and included - and modified when necessary - items that we deemed relevant in the Finnish OHS context. The third main component of the new scale, in addition to the core extracted from the two previous questionnaires, was the process of EBHC and the concept of EBP as outlined in the JBI model [1, 2]. The development process resulted in a questionnaire with 15 Likert-scale items measuring occupational health professionals' attitudes, competence, and organisational support for EBP. Responses are given using a 5-point Likert scale with the response options: "Fully agree", "Agree", "Somewhat disagree", "Fully disagree", and "I cannot say". During practical testing with OHS professionals, we supplemented the core items with background questions,

Table 1. Participant characteristics of our in-development questionnaire respondents.

Variables	% (N)
Age	
20-29 years	9.9 (52)
30-39 years	25 (131)
40-49 years	25.6 (134)
50-59 years	26.7 (140)
60-69 years	12.8 (67)
Workplace	
Private OHS company	78.4 (411)
Public OHS company	9.5 (50)
Employer-owned OHS	6.7 (35)
OHS owned jointly by several employers	2.9 (15)
Working role	
Occupational health physician	25.8 (135)
Occupational health physician role combined with supervisory or expert tasks	5.9 (31)
Occupational health nurse	52.1 (273)
Occupational health nurse role combined with supervisory or expert tasks	3.1 (16)
Supervisor or expert role	13.2 (69)
Work experience in OHS	
Less than five years	28.8 (151)
5-10 years	22.9 (120)
11-20 years	29.6 (155)
Over 20 years	18.7 (98)
Work experience in supervisory, development or expert tasks	
No experience	54.8 (287)
Less than five years	21.8 (114)
5-10 years	11.6 (61)
11-20 years	8.4 (44)
Over 20 years	3.4 (18)

OHS: Occupational Health Service.

by the PCA, with the lowest acceptable value being 1. We evaluated the items using communalities with values between 0 and 1, where higher values indicate more communality.

We used Cronbach's alpha to evaluate the scale's reliability, also called internal consistency. A high

open questions, and questions measuring information sources used, consistent practices in OHS and methods to develop and support EBP.

In phase 2, we tested the scale's content validity in two steps. First, ten OHS or EBHC experts evaluated the scale using a purpose-built form designed to assess the relevance and clarity of each item. The expert group comprised five occupational health nurses, four occupational health physicians and one Finnish Nursing Research Foundation expert. Two specialised occupational health physicians commented on the scale in the second step. We computed a content validity index (I-CVI) [15] using item relevance ratings from our content experts. Items achieving an I-CVI of 0.78 or higher for three or more experts can be considered evidence of good content validity [15].

In phase 3, the questionnaire was completed by an opportunity sample of 524 Finnish physicians and nurses working in OHS. This sample size is sufficient given that most prior EBP assessment instruments have been developed using a sample ranging from 101 to 500 participants [8]. The questionnaire was available for respondents online from November 2020 to August 2021.

Following the principle of informed consent, we informed respondents in the cover letter about the purpose of the study, the respondents' anonymity and voluntariness, the confidentiality of data and the contact information of the researchers and partner organisations cooperating with the study. We also made a data privacy notice publicly available that was compliant with EU GDPR requirements. According to the ethical principles of research conducted with human participants in Finland, there was no need to obtain ethical approval for this study [16].

We estimated the questionnaire's construct validity using exploratory factor analysis (EFA). First, we used the Kaiser-Mayer-Olkin Measure of Sampling Adequacy to test the suitability of the data for EFA. A KMO value 0.9 confirmed that the sampling was adequate (0.8–1) for EFA. We performed a principal component analysis to examine the construct validity of the 15 Likert-scale items measuring occupational health professionals' attitudes, competence, and organisational support. We determined the emerging factors by using the eigenvalues generated

Table 2. Factor matrix.

Item	F1	F2	F3	Communalities
Evidence-based practice is a strategic objective for our organisation	**.758**	.072	.239	.636
Our organisation values evidence-based practice	**.791**	.129	.294	.729
My organisation encourages staff to use evidence-based information	**.819**	.103	.249	.743
Staff is regularly offered internal training about up-to-date, evidence-based information in occupational health care	**.664**	.273	-.010	.516
Staff is regularly offered external training about up-to-date evidence-based information in occupational health care	**.613**	.248	-.164	.464
Within my organisation, new evidence-based information is shared actively and for all employees	**.754**	.248	.017	.630
When new research evidence emerges, my organisation evaluates the concordance of existing guidance and practices with the new evidence	**.665**	.236	-.047	.500
I use evidence-based information regularly in my work	.289	**.672**	.225	.586
I can choose evidence-based OHS for an individual client	.100	**.805**	.175	.689
I can choose evidence-based OHS for workplaces	.230	**.776**	-.082	.662
I can justify to my clients the choices I make in OHS by using evidence-based information	.237	**.734**	.181	.627
I make use of treatment guidelines in my work	.084	**.511**	.312	.366
I use evidence-based information to justify the need for change in OHS	.253	**.509**	.211	.368
I think it's important that OHS activities and guidance are evidence-based	.112	.214	**.815**	.722
I think it's important that my own activities as an OHS professional are evidence-based	.058	.276	**.844**	.793

OHS: Occupational Health Service.

Table 3. Factor model of three factors.

Factor name	Items	Communalities	Explained variance	Eigen-values	Factor loading
Organisational support	7	0,464–0.743	38.8	5.8	0.613–0.819
OHS practitioners' competence	6	0.366–0.689	13.1	2.0	0.509–0.805
OHS practitioners' attitude	2	0.722–0.793	8.4	1.3	0.815–0.844

value of Cronbach's alpha (0.7 or higher) indicates internal consistency [15, 17].

3. Results

Based on expert evaluation (n=12) and content validity index (I-CVI), we determined the scale's content validity to be good. Following the expert ratings, we dropped items that failed to reach a CVI-I level of 0.78 or higher (data not shown). The recruited experts confirmed the scale is based on a sound theoretical footing of evidence-based health care in the OHS context. The experts had suggestions regarding the clarity of some items, so they were reworded.

We obtained an opportunity sample of 524 respondents from the scale's target population. Fifty-five percent of the respondents (n=289) were occupational health nurses, 32% (n=166) were occupational health physicians, and the remaining 13% (n = 69) were experts and supervisors. See Table 1 for a description of the respondents.

Table 4. Items of the EBP-OHS.

Organisational support	Evidence-based practice is a strategic objective for our organisation
	Our organisation values evidence-based practice
	My organisation encourages staff to use evidence-based information
	Staff is regularly offered internal training about up-to-date evidence-based information in occupational health care
	Staff is regularly offered external training about up-to-date evidence-based information in occupational health care
	Within my organisation, new evidence-based information is shared actively and for all employees
	When new research evidence emerges, my organisation evaluates the concordance of existing guidance and practices with the new evidence
OHS practitioners' competence	I use evidence-based information regularly in my work
	I can choose evidence-based OHS for an individual client
	I can choose evidence-based OHS for workplaces
	I can justify to my clients the choices I make in OHS by using evidence-based information
	I make use of treatment guidelines in my work
	I use evidence-based information to justify the need for change in OHS
OHS practitioners' attitude	I think it's important that OHS activities and guidance are evidence-based
	I think it's important that my own activities as an OHS professional are evidence-based

OHS: Occupational Health Service.

Using principal component analysis, we identified three factors explaining 60.3% of the total variance. The communalities varied between 0.37–0.79, indicating that the items measured the factors reliably. Factor loadings varied between 0.51–0.84. Three factors emerged from the factor analysis: Organisational support (seven items), OHS practitioners' competence (six items) and OHS practitioners' attitude (two items) (see Tables 2 and 3).

Table 4 presents the factor structure and items of the 15 Likert-scale items that achieved a Cronbach's alpha of 0.88, showing good reliability.

4. Discussion

We developed and psychometrically tested a 15-item measure of evidence-based practice in OHS. The results revealed that the scale has good psychometric properties. Based on PCA, the measure consists of three domains. The first domain of the scale, 'Organisational support', consists of seven items that focus on the organisation's role in EBP and how it supports and encourages staff to perform EBP. This includes organisational values towards EBP and practical activities, such as providing training (at or outside the workplace) about evidence-based information and what to do with it.

Additionally, the first domain incorporates the perspective of quality assurance, involving information sharing and ensuring alignment of guidance and practices with new evidence. Organisational support is linked to management in creating a culture for EBP and enabling competence, support, and resources. Previous studies have also highlighted the significance of organisational and managerial support, often lacking in the occupational health context [6, 20]. Drawing on these findings, measuring support at the organisational level can facilitate recognising managerial or organisational development needs in this area.

The second domain, 'OHS practitioners' competence,' comprises six items. This domain describes the role of employees, what they do, and their proficiency in performing EBP. Regarding concrete actions, the domain items assess the use of evidence-based information at work and how it is

applied to justify necessary changes in OHS. Regarding competence, the domain measures respondents' ability to choose evidence-based services for individual clients and workplaces. The third domain focuses on OHS practitioners' attitudes and consists of two items. These items measure how important it is to the employees that occupational health services and their professional activities are based on evidence. Previous studies have identified positive attitudes towards EBP [4, 20]. Attitudes are pivotal in achieving truly evidence-based practice and require regular evaluation. Identifying OHS professionals' competence and attitudes facilitates the evaluation of their educational needs.

The EBP-OHS scale can measure the extent of organisational support for EBP in occupational health services and employee competence and attitudes toward EBP. The scale is divided into two levels: the organisational and employee levels. The organisational level (organisational support) is built upon the JBI Model of Evidence-based Healthcare, and its evidence transfer segment. Evidence transfer refers to disseminating knowledge to individual health professionals and systems [1, 18]. The evidence transfer segment includes education, systems integration, and active dissemination.

On the other hand, the employee level (OHS practitioners' competence and attitudes) embodies the evidence implementation segment in the same JBI Model. Evidence implementation refers to activities that engage key stakeholders with evidence to inform decision-making and enhance the quality of healthcare services [1, 18]. The evidence implementation segment of the JBI model consists of context analysis, facilitating change and evaluating processes and outcomes. In this phase, evidence-based practice becomes a concrete reality in OHS through decision-making both at the enterprise level and that of individual service users.

The EBP-OHS is a new validated tool for measuring evidence-based practice in OHS. It focuses on EBP concerning physicians and nurses, regardless of whether they are involved in patient care, administration, or both. This new scale expands the range of tools available for OHS as previous ones have focused on primary health care and nurses, such as EBPQ [11] and Quick-EBP-VIK [12], or solely on occupational health physicians [4]. The EBP-OHS offers several avenues for supporting the development of evidence-based practice. It enables comparisons both cross-sectionally (between units or organisations) and prospectively (within the same unit or organisation over time). Within-organisation comparisons facilitate allocating development resources according to needs, whereas over time comparisons enable setting achievable and measurable goals and supporting continuous development. The scale is likely most relevant when used in countries with similarly organised occupational health services, such as the Netherlands and other Nordic countries.

The EBP-OHS is based on a previous tool developed within nursing science, and it builds upon a valid and intuitive theoretical understanding of evidence-based practice [1] whilst acknowledging the requirements of the occupational health arena. Unlike the Fresno scale, which focuses on the skills required to find and understand scientific evidence [9], the EBP-OHS starts with the assumption that respondents are already familiar with the basics of EBM. This way, the respondents are free to explore how they feel about how evidence is transferred and implemented into practice within their organisation. In other words, the EBP-OHS and Fresno scales may be considered mutually complementary.

When compared to similar studies (cf. [8]), one strength of ours is the large sample size used (N=524). So far, the tool has been tested only in Finland. We support efforts to conduct a cross-cultural validation study.

5. Conclusion

Based on its psychometric properties, the EBP-OHS is a valid scale to measure evidence-based practice within OHS. The scale is a practical tool that substantiates relevant theory, specifically the phases of evidence transfer and implementation of the JBI Model of Evidence-Based Healthcare into the OHS context.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and the ethical principles of research conducted with human participants in Finland. Ethical review and approval were waived for this study due to the chosen methodology in which participants could decide if they chose to participate based on a detailed description of how the study would obtain, analyse and publish results based on the data participants would provide anonymously. According to the guidance provided by the Finnish National Board on Research Integrity, studies of this kind do not need to obtain a priori ethical approval.

Informed Consent Statement: Responding to the questionnaire was deemed equal to providing informed consent.

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Author Contribution Statement: J.R. and K.P. contributed to the design and implementation of the research, to the analysis of the results, and to the writing of the manuscript. K-P.M. and T.O. contributed to the writing of the manuscript.

Declaration on the use of A.I.: None.

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Nightshift Rotation Schedule and Fatigue in U.K. and Italian Nurses

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Keywords: Nightshift Work; Epworth Sleepiness Scale; Daytime Sleepiness; Shift Schedule; Healthcare Workers

Abstract

Background: *Whether hours on shift might impact adaptation to night shift work is still controversial.* **Methods:** *We conducted a pooled analysis of two studies, including 170 hospital nurses working night shifts, 116 from a United Kingdom study working 12-hour rotating shifts, and 54 from Italy working 8-hour shifts. Both studies used the Epworth Sleepiness Scale (ESS) to detect sleepiness during routine daytime activities as an indicator of fatigue. We compared the prevalence of daytime sleepiness, as indicated by an ESS score≥11, resulting from either shift work schedule. We used logistic regression to calculate the risk of daytime sleepiness associated with 12-hour vs. 8-hour nightshifts, adjusting by age, sex, and parenting children aged≤4.* **Results:** *When comparing similar work circumstances, nightshifts prolonged to 12 hours did not increase the risk of daytime sleepiness compared to 8 hours (OR=0.9, 95% CI 0.32, 2.59).* **Conclusions:** *Our results suggest that 12-hour rotating nightshifts with additional rest days and 8-hour rotating shift schedules do not differ in their impact on daytime sleepiness. Further research is warranted on what strategies might effectively contrast fatigue, circadian misalignment, and the related metabolic changes leading to adverse health outcomes, including cancer.*

1. Introduction

Working against the regular circadian rhythm has well-recognized detrimental effects on worker's health, including sleep problems, cardiovascular disorders, and metabolic disorders, and it is classified as a probable human carcinogen by the International Agency for Research on Cancer (IARC) [1]. Nonetheless, continuous care of patients requires hospital workers to rotate on a 24-hour schedule, including night shifts, defined as work for more than three hours between 23:00 - 6:00 am.

Nightshift work-induced circadian disruption can lead to sleep loss, poor sleep quality, and excessive daytime sleepiness. During the night shift, sleep deprivation may cause drowsiness and fatigue in the healthcare staff, resulting in poor work performance, diminished healthcare quality, higher risk of medical errors, and road traffic accidents in commuting back home [2]. Such events are well described in nurses working night shifts [3, 4]. Epidemiological studies of chronic circadian disruption are complicated by internal and external factors that modulate the adaptation of the internal clock to changes in the light/

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dark cycle when moving closer to the Earth's poles, or crossing time zones or its alignment to maintain a vigilant state of active wake at nighttime when engaged in nightshift work. Internal factors include gene polymorphisms, including the clock genes [5] expressing the individual chronotype, age, sex, and health issues; external factors enlist brightness and wavelength of lighting during working hours, the possibility of regular, resting sleep in the daytime in a quiet and dark ambient, and social restraint. Intrinsic characteristics of shift work schedules, such as shift duration, the direction of shift rotation, the number of consecutive night shifts, and days of rest in the rotation scheme contribute to accelerating or delaying nightshift work adaptation [6]. Studies on nightshift work and cancer were conducted in different latitudes, populations, and workplaces with diverse shift work schedules; results were not always consistent, which might reflect the challenge posed by the complex intertwining of multiple factors [1, 7, 8], including variations in the shift duration and rotation schedule.

In the 1990s, several countries, including the United States and the United Kingdom, adopted daily 12-hour rotating work shifts to overcome hospital staff shortages and reduce the cost of healthcare. Currently, such a scheme extends to 45% of hospitals in the United Kingdom and 70% in the United States, while it is less frequent in Europe (16%) and Oceania [9]. Initially, the introduction of 12-hour shifts was well received, particularly among female nurses with children, because of the reduction of weekly work shifts and more days off work, substantial savings in money for childcare, travel, and time, and potential improvement in life balance [10].

However, it is still unclear whether any increase in daytime sleepiness, fatigue, and metabolic changes, typical of circadian disruption, might result from adopting a 12-hour instead of 8-hour nightshift schedule. A survey among 152 Australian nurses showed that the proportion of those satisfied with the shift schedule rose three times after introducing 12-hour shifts [10]. Most participants reported beneficial health effects of 12-hour shifts: the communication with senior staff improved, the number of hours of professional development leave increased, and the annual sick and family leave days decreased. Adverse health outcomes in the patients did not increase in frequency after introducing the 12-hour shift roster [10]. However, in a U.S. survey covering 71 acute care nonfederal hospitals in Illinois and North Carolina, longer working hours were associated with fatigue, decreased alertness, and higher frequency of adverse health outcomes in the patients [11]. Also, nurses' sleeping hours were significantly less following a 12-hour shift, and sleepiness during the working hours increased from the beginning to the end of each night shift and with the number of night shifts throughout the week [12].

An extensive European survey showed that nurses from 12 countries perceived the 12-hour shift and working overtime as linked to lower quality and safety at work [13]. Compared to nurses on 8-hour shifts, those engaged in 12-hour shifts rated the quality of nursing and patients' safety as poor 30% more frequently and the care left incomplete at the end of the work shift 13% more frequently [13].

We pooled data from two reports on sleep quality and alertness in nurses using the same methodology in the United Kingdom [14] and Italy [15]. The U.K. study results showed a correlation between work safety issues and accidents when driving to commute back home after a night shift [14]. The Italian study suggested an excess risk of daytime sleepiness among female but not male nurses [15]. As different shift duration and rotation schemes were applied in the U.K. and Italian hospitals contributing to those studies, we selected nurses engaged in nightshift work from the respective database to explore whether longer hours on shift might increase the risk of daytime sleepiness, taken as an indicator of fatigue and sleep loss.

2. METHODS

We pooled the data from two published reports on fatigue among nurses and midwives in the United Kingdom and Italy [14, 15]. Both studies had a cross-sectional study design, relied on voluntary participation, and, following the signature of an informed consent form, used an anonymous, self-administered questionnaire and the

Epworth Sleepiness Scale (ESS) to assess daytime sleepiness.

The ESS is a validated tool to assess daytime sleepiness at all ages, consisting of eight items that evaluate, on a scale from 0 to 3, the propensity to fall asleep in different situations of daily life, such as in front of the TV, while driving, or in a public place. Therefore, the sum of the scores on the scale can range from 0-24. A higher ESS score relates to an increased level of daytime sleepiness, with values ≥ 11 indicative of abnormal sleepiness [16].

Apart from using the same protocol, an additional reason for combining two study populations from different countries was that exploring the effect of a longer duration of the night shift would have been impossible in Italy, where work contracts stipulated between the unions and the association of employers regulate nationwide matters such as working hours and the shift schedule. In the United Kingdom, 229 nurses and midwives (211 female and 18 male, 12% of the total workforce) from the Newcastle-upon-Tyne NHS Hospitals Foundation Trust working night shifts participated in the study. Data collection lasted from 16/03/2020 to 01/06/2020 [14]. The rota varies between wards and individual staff, with no uniform schedule or policy. Following a sharp rise in the proportion of U.K. nurses working 12 hours or longer in NHS hospitals, from 31% in 2005 to 51% in 2009 [17], nightshifts typically start anytime between 7-10 pm and run for 10-12 hours [18]. Twenty-two participants who worked permanently at night and 91 who had worked three or more consecutive nights were excluded from this analysis, leaving 116 subjects available for study. The U.K. study was conducted in the months of exponential growth of the COVID-19 pandemic when the doubling time for infection was 2.2 days [19]. Therefore, to account for the emergency circumstances that might have contributed to sleep deprivation, fatigue and daytime sleepiness in the frontline departments, we divided the U.K. nurses into two groups: 1. frontline departments (No.=46), including the 34 respondents from Anaesthetics & Critical Care, and 12 from Medicine units; and 2, other departments where the admissions were less affected by the pandemic (No.=70), including the 38 respondents from the Paediatric and Neonatal care, 19 from Surgery, and 13 from Obstetrics and Gynecology.

In the Italian study, all 43 female and 22 male nurses from the Cagliari University Hospital, whose annual visit with the occupational physician to assess their fitness for the job was scheduled in June -July 2018, had filled out a similar questionnaire [15]. We excluded ten female and one male participants, who only worked fixed daytime shifts five days a week. The remaining 54-night shift workers 54 (33 females and 21 males, 83%) were included in this pooled analysis. The following regular 8-hour forward rotating shift schedule was applied: two consecutive morning shifts (M), two consecutive postmeridian shifts (E), one single night shift (N), and two rest days (R) (MMEENRR). Night shifts typically start at 10:00 pm and end at 6:00 am. Because of the staff shortage during the holidays, the August and December rota included two consecutive night shifts before the rest days (MMEENNRR).

2.1. Statistical Methods

We used the median and interquartile range (IQR) to compare the central tendency and spread of the ESS score among the UK and Italian nurses and the Mann-Whitney test. We compared categorical variables between the two study populations with Pearson's chi-square or a goodness-of-fit chi-square test when categories were more than two. The 5% α error threshold was assumed to reject the null hypothesis. First, we used univariable analysis to explore the association between the covariates and daytime sleepiness as defined by an ESS score ≥ 11. Then, we used logistic regression analysis to investigate whether the 12-hour nightshift schedule used in the U.K. hospitals might increase the risk of daytime sleepiness compared to the 8-hour shift adopted in the Italian hospitals, adjusting by age and parenting children aged ≤ 4. BMI did not show an association nor decrease the residual variance of the model once included as a covariate. The Odds Ratio and its 95% Confidence Interval (95% CI) was the measure of association.

The two studies were conducted according to the indications of the Declaration of Helsinki and approved by the local Ethics Committees, the

Comitato Etico Indipendente of the Cagliari University Hospital (Protocol No. PG/2018/17165) and the University of Manchester Research Ethics Committee (2020-8652-12800). The UK study also received approval from the Health Research Authority (HRA) – Research and Development (R&D) for NHS research through the Integrated Research Application System (IRAS) (268824) in 2020.

3. Results

Table 1 shows selected features of the two study populations. The average duration of the night shift was 12 hours (range 10.5–13) for the U.K. nurses and 8 hours for Italian. Nurses from the U.K. hospital were more frequently female, with ≤4-year-old children, and overweight/obese. The age distribution and the prevalence of daytime sleepiness, as detected by an ESS score≥11, did not differ significantly between the two hospitals (χ^2=3.58, degrees of freedom [df]=6, p=0.733 and χ^2=1.35, df=1, p=0.246, respectively).

In the univariable analysis, having ≤4-year-old children was associated with an increase in the risk of daytime sleepiness (OR=2.1, 95% CI 0.97, 4.71). Overall, men were half as likely as women to suffer from daytime sleepiness (OR=0.5, 95% CI 0.16, 1.43). However, among the U.K. nurses, the prevalence of an ESS score ≥ 11 did not vary by sex;

Table 1. Selected variables among the nurses of two hospitals in the United Kingdom, working 12-hour nightshifts, and Italy, working 8-hour nightshifts.

	United Kingdom (N=116)	**Italy (N=54)**	
	N (%)	**N (%)**	***p* - value**
Age			
≤ 29 years	43 (37.1)	17 (31.5)	0.733
30 – 39 years	36 (31.0)	16 (29.6)	
40 – 49 years	23 (19.8)	15 (27.8)	
≥ 50 years	14 (12.1)	6 (11.1)	
BMI			
≤ 24.9	43 (37.1)	43 (79.6)	<0.001
25 – 29.9	43 (37.1)	7 (13.0)	
≥ 30	30 (25.8)	4 (7.4)	
Sex			
Women	109 (94.0)	33 (61.1)	< 0.001
Men	7 (6.0)	21 (38.9)	
Parenting children aged ≤ 4			
yes	32 (27.6)	4 (7.4)	0.003
no	84 (72.4)	50 (92.6)	
Department			
Non- frontline	38 (32.8)	-	
Frontline	78 (67.2)	-	
ESS score			
≥ 11	31 (26.7)	10 (18.5)	0.244
≤ 10	85 (73.3)	44 (81.5)	

*Note: P-values from χ^2 tests; * p < 0.05.*

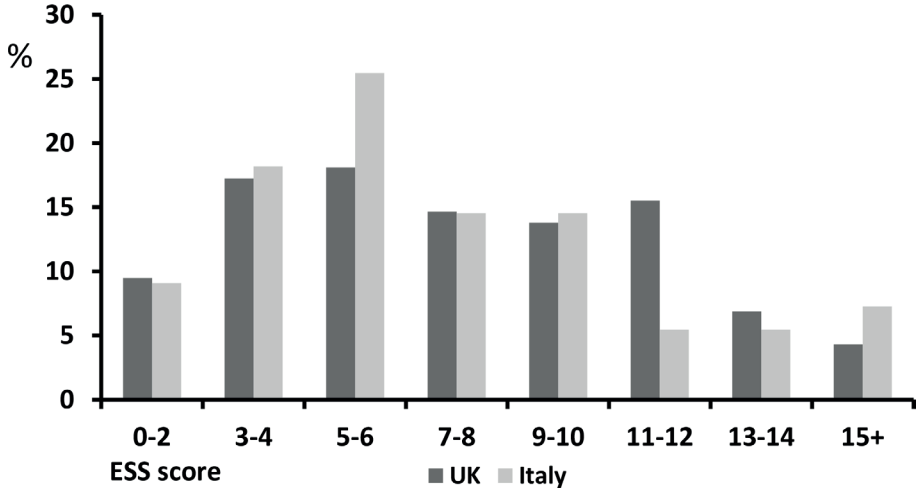

Figure 1. Frequency distribution of the ESS score in UK and Italian nurses.

however, male nurses among the 116 selected for this analysis were only 7.

To double-check whether the occurrence of the COVID-19 pandemic at the time of recruiting the U.K. study population increased fatigue, sleep deprivation, and daytime sleepiness in the frontline hospital departments, we compared the prevalence of ESS scores≥11 among U.K. nurses in critical care units (Anaesthetics and Critical Care and Medicine), *vs.* other departments (Paediatrics and Neonatology, Obstetrics and Gynaecology, and Surgery). The univariable analysis suggested that, over the whole study population, daytime sleepiness was slightly more prevalent among the U.K. than the Italian nurses (OR=1.6, 95% CI=0.72-3.57).

However, the graph in Figure 1 shows that the frequency distribution of the ESS score between U.K. and Italian nurses is substantially similar; the median ESS score was 7 (interquartile range [IQR] 4-11) among the U.K. nurses and 6 (IQR 4-9.75) among the Italian and (Mann Whitney test=-0.61, p=0.542).

In the multivariable logistic regression analysis to predict an ESS score suggestive of daytime sleepiness, we included the following covariates to reciprocally adjust the respective effects: age, sex, parenting children aged ≤4, and a binary category for shift duration, 12 hours in the U.K. and 8 in Italy. To account for the additional burden due to the stressful working conditions associated with the COVID-19 pandemic at the time of recruiting the U.K. study population, we first run a model including all study subjects, then after excluding the U.K. nurses working in frontline or non-frontline departments, alternatively. Table 2 shows the results. In all instances, the statistical power was insufficient to exclude chance as the determinant of the observed point estimates. Still, the results suggest that a 10-year increase in age, female sex, and parenting children aged ≤ 4 were risk factors for daytime sleepiness (OR=1.3, 95% CI 0.94–1.90; OR=1.8, 95% CI 0.54, 6.04; and OR=2.1, 95% CI 0.90, 4.75, respectively). Overall, the risk of daytime sleepiness was not elevated in U.K. nurses working 12-hour night shifts compared to the Italian nurses working 8-hour night shifts (OR=1.2, 95% CI 0.50–2.97). It lowered after excluding the frontline U.K. nurses during the COVID-19 pandemic (OR=0.9, 95% CI 0.32, 2.59). U.K. nurses in the frontline during the pandemic had a moderate increase in the risk of daytime sleepiness, which was similar compared to the Italian nurses (OR=1.5, 95% CI 0.56, 4.06) and the U.K. colleagues working in other departments (OR=1.5, 95% CI 0.63, 3.75) (not shown in the Table).

4. Discussion

Several features of shift work might imply more or less severe fatigue and circadian disruption; these

Table 2. Results of the logistic regression analysis on the risk of daytime sleepiness, as indicated by an ESS score ≥ 11, associated with nightshift duration (12 hours vs. 8 hours) and personal covariates. The first column includes all the UK nurses; the second includes only the UK nurses in non-frontline departments; the third includes only the UK nurses in the frontline departments.

	All the study population (ESS ≥ 11, No.= 41; ESS ≤ 10, No.=129)	**Only non-frontline UK nurses (ESS ≥ 11, No.= 27; ESS ≤ 10, No.= 97)**	**Only frontline UK nurses (ESS ≥ 11, No.= 24; ESS ≤ 10, No.= 76)**
Covariates	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**
Age (per 10-year age-group)	1.3 0.94 - 1.90	1.2 0.76 - 1.79	1.2 0.76 - 1.99
Female Sex	1.8 0.54 - 6.04	1.8 0.42 - 7.74	2.6 0.67 - 10.3
Parenting children Aged ≤ 4 years	2.1 0.90 - 4.75	2.7 0.98 - 7.35	1.5 0.39 - 5.72
12-hour (UK) *vs.* 8-hour (Italy) nightshift	1.2 0.50 - 2.97	0.9 0.32 - 2.59	1.5 0.56 - 4.06

include forward or backward rotation shift schedules, rotation speed, number of consecutive night shifts, and shift duration [20-22]. In this paper, we explored whether; after adjusting for age, sex, and parenting children < 4 years old, a longer nightshift duration might affect the risk of daytime sleepiness as an indicator of fatigue. Our results suggest that 12-hour forward rotating shifts, including night shifts, do not increase the frequency of self-reported daytime sleepiness compared to 8-hour rotating shift schedules.

If longitudinal trials supported by adequate statistical power confirm them, prolonging night shifts up to 12 hours and allowing additional rest days would not affect daytime sleepiness, fatigue, and, possibly, other adverse health outcomes related to shift work more than a rotating 8-hour shift schedule. Other shift work schedules or individual covariates might be more important risk factors. Although with insufficient statistical power, our results confirm previous reports about the association between parenting children aged ≤ 4 with shorter sleep duration and lower sleep quality, two determinants of daytime sleepiness [23, 24]. Our finding of an increased risk of daytime sleepiness among female nurses is also consistent with previous reports of a higher frequency of insomnia, daytime sleepiness, and poor sleep quality among women in general and particularly among female night shift workers [15, 25].

Previous reports evaluated job satisfaction [10, 20], the shift rotation speed [20], patients' outcomes [11], and perceived patients' safety and quality of care [13] or described sleep, sleepiness, fatigue, and performance in 12-hour nightshift vs. daytime nurses [12] but not the direct effects of prolonged nightshift hours on daytime sleepiness. Various drivers might orientate the nurses' preference about hours and type of shift schedule: an older age was a factor for preferring shorter shifts. At the same time, marital status and parenting children were associated with a preference for longer shifts [26]. Other factors, such as the chronotype, the commuting time, and the physical strain associated with the job, might contribute. Overall, when staff were involved in decision-making and personal preferences were taken into account, both acceptance of shifts and job satisfaction were higher [26]. In New York state, compared to nurses working 8-hour shifts, 12-hour shift workers were more frequently happy with their jobs, more likely to be satisfied with their shift schedule, less emotionally exhausted, and less likely to report missing shifts. Besides, units with 12-hour shifts had lower vacancy rates and weeks required to fill the vacant positions. Patient outcomes did not differ [27]. It is quite possible that the additional days of rest per week, the saving of weekly time and money for commuting, and the extra time available for family or leisure activities might compensate for the increased fatigue at the end of the work shift; still, longer working hours imply more fatigue, the risk of burnout, and a higher frequency of intention to leave [28]. A European survey showed that nurses from 12 countries

perceived the 12-hour shift and working overtime as causes of lower quality and safety at work; compared to nurses on 8-hour shifts, those engaged in 12-hour shifts rated 30% more frequently as poor the quality of nursing and the patient's safety, and 13% more frequently the care left undone at the end of the work shift [13].

Indeed, fatigue increases from the beginning to the end of a 12-hour shift, as suggested by a decrease in the work pace and no change in energy expenditure and heart rate [29]. However, in the study of U.K. nurses, the number of consecutive night shifts worked at the time of data collection was not a predictor of daytime sleepiness in the univariable analysis and was not explored further [14]. Currently, the U.K. Health and Safety Executive guidance recommends a shift duration not exceeding 12 hours, no more than 2-3 consecutive night shifts, and a minimum rest time between shifts of 11 hours [30]. 8-hour shifts are recommended when work is monotonous and physically demanding, concentration is required, is conducted in isolation, presents safety issues, or implies exposure to physical or chemical hazards. 12-hour shifts require frequent breaks to reduce fatigue, adequate recovery time between shifts, and consideration of the contribution to fatigue by commuting time and availability of public transport [30]. In Italy, the nurses' working time is regulated through the national collective contract: the regular weekly working hours are 36, and work shifts may last from 6 to 7 hours and 12 minutes but can extend up to eight hours with one extra paid hour. The maximum consecutive hours allowed is 12 hours and 50 minutes, and the minimum resting time between shifts is 11 hours. A 12-hour shift is considered a double shift [31].

Several weaknesses limit the interpretation of our results. First, both original studies used a cross-sectional study design, which raises doubts about the link between symptoms and the current engagement in night shift work. The most resilient nurses might have been selected for shift work, while that incapable of adapting moved to a more tolerable work schedule. However, we compared two populations of night shift workers, both presumably selected for their resilience.

The small size and non-random selection criteria of the study population contributing to our pooled analysis may but allow tentative remarks as none of our results could exclude chance as the determinant. Because of the exploratory nature of our study, we pooled the data sets of two published reports without conducting prior statistical power calculations. A *posterior* calculation indicates that, with our study size, we might have estimated a 4-fold risk of daytime sleepiness associated with a 12-hour night shift schedule, with 80% statistical power ($\beta = 0.20$) and an α-error of 5%. We did not detect an excess risk, but we can only exclude a greater than 4-fold risk, which indicates that a substantial risk increase might still occur. Therefore, we interpret our findings as preliminary and hope they might stimulate further research on the most appropriate work organization to reduce fatigue and prevent fatigue and the other adverse health outcomes associated with night shift work.

A further major limitation of our study is that it addresses daytime sleepiness as an indicator of sleep loss, fatigue, and circadian disruption, the condition leading to oxidative stress, immune suppression, and the pro-inflammatory status responsible for the excess risk of cancer and other health outcomes reported in the majority of shift work studies [1]. We used the ESS tool, which is popular among sleep scientists worldwide. We are confident that minor language changes to adapt it to country-specific cultural issues did not impair the international comparability of the resulting scores. However, although a standardized questionnaire was used, socio-cultural differences between the two countries might have influenced the frequency of reporting symptoms and, therefore, the ESS score. Nevertheless, the ESS is a subjective report of symptoms and, thus, subject to error depending on the level of job satisfaction, as previously mentioned. We aimed to compare daytime sleepiness in nurses working 12-hour vs. 8-hour shifts. Due to the lack of a wider within-country variation, we had to compare nurses from two countries by excluding nurses working only daytime shifts from both datasets and, from the U.K. dataset, nurses who worked three or more consecutive nights before the interview and those working permanently on night shifts. Poor job satisfaction might have occurred in both study populations, attenuating the bias on the risk estimate. However, we cannot exclude that, among the U.K. nurses, a

greater acceptance because of more free time might have resulted in fewer sleepiness symptoms, thus reducing their ESS score and biasing towards the null their hypothetic greater risk compared with the briefer 8-hour shift.

The two studies contributing to this pooled analysis were separated two years, and the U.K. study recruited participants during the exponential growth of the COVID-19 epidemic. To preserve the comparability between the two study populations, we first excluded those who had worked more than two-night shifts at the time of the interview; then, we conducted a secondary analysis after excluding nurses from critical care units. Although the results were substantially confirmed, this procedure further reduced the study population size and the statistical power of the analysis.

Besides, the two-year lag between the recruitment of the two study populations, socio-economic differences between the two countries, and, most of all, the incumbent COVID-19 pandemic at the time of recruiting for study the U.K. nurses might have introduced important, uncontrolled sources of bias making it more difficult to interpret our findings. We are also aware of being unable to exclude chance as a determinant of our observation. Still, some published reports agree with our findings, and we thought that, although statistically weak, they might foster interest in conducting further research with larger data sets.

5. Conclusion

Further research with a prospective study design and adequate statistical power is warranted to confirm or reject whether adopting a 12-hour instead of an 8-hour nightshift schedule might increase daytime sleepiness, fatigue, and metabolic changes typical of circadian disruption.

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Institutional Review Board Statement: The two studies were conducted following the Declaration of Helsinki and approved by the local Ethics Committees, the Comitato Etico Indipendente of the Cagliari University Hospital (Protocol No. PG/2018/17165) and the University of Manchester Research Ethics Committee (2020-8652-12800). The UK study also received approval from the Health Research Authority (HRA) - Research and Development (R&D) for NHS research through the Integrated Research Application System (IRAS) (268824) in 2020 animals.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Declaration of Interest: The Authors declare no conflict of interest.

Author Contribution Statement: LR and AW wrote the original manuscript; MP, MvT, and PC and BC contributed to the design and implementation of the research; MF and EM contributed to the analysis of the results, and PC contributed to the writing of the manuscript. All coauthors reviewed and approved the final manuscript.

Declaration on the use of AI: None.

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Factor Structure, Psychometric Properties, and Measurement Invariance of the Pandemic Experiences and Perceptions Scale Among Italian Hospital Workers

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Keywords: Psychometrics; Pandemic Experiences and Perceptions Scale; Measurement Invariance; Exploratory Structural Equation Modelling; COVID-19 Pandemic

Abstract

Background: *The COVID-19 pandemic represented substantial risks to hospital workers' physical and mental health. The availability of validated measures on the impact of the pandemic on workplaces is crucial for developing data-driven interventions. The primary purpose of our study was to translate it into Italian and assess factor structure, psychometric properties, and measurement invariance of the Pandemic Experiences and Perceptions Scale (PEPS).* **Methods:** *The survey was completed by 766 workers from an Italian hospital. We examined the internal structure of the PEPS using confirmatory factor analyses (CFA) and exploratory structural equation modeling (ESEM) techniques and testing the invariance for clinical vs. nonclinical workers.* **Results:** *The six-factor ESEM solution showed an excellent fit to the data (CFI=0.956, TLI=0.932, RMSEA=0.050), supporting the superiority of the ESEM solution. The factorial invariance of the PEPS across occupational roles (clinical vs. nonclinical hospital workers) was supported, and the ESEM-based McDonald's omega was good for all factors.* **Conclusions:** *The results from this study provided evidence for the factorial validity, reliability, and measurement invariance across occupational roles of the Italian version of the PEPS. Thus, the Italian version of the PEPS is a reliable and valid tool for assessing pandemic experiences and perceptions among Italian workers.*

1. Introduction

The COVID-19 pandemic has dramatically impacted our lives, causing significant challenges and shaping the future of our societies [1]. The pandemic changed the risk perception process because it has been a global event capable of changing people's behaviors toward risk. In the working context, occupational health and safety measures were crucial in protecting the workforce, especially for those directly engaged in fighting the pandemic, such as healthcare workers (HCWs) [2–4]. In the first year of the pandemic, many studies have been developed to explore how the pandemic impacted individuals' mental health. Recent systematic reviews synthesized the results of those studies, showing that HCWs had to face many challenges, including higher risk of infection and inadequate personal

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protective equipment (PPE) [5, 6], fear of infecting family and loved ones [7], increased workloads, and longer working hours [5, 8], increased work-life imbalance, decreased mental health, and sleep disorders [5, 9, 10].

However, these extreme events and the reactions that HCWs experienced are significant issues that need greater consideration regarding how pandemic-related perceived risks can be assessed. Recently, the World Health Organization (WHO) emphasized that, despite the focus on collecting data to understand the impact of the pandemic on the workforce, most of the studies were conducted adopting no pandemic-specific surveys [2, 11]. Especially at the beginning of the pandemic, most of the newly developed measures focused on assessing COVID-19-related mental health reactions such as fear [12], anxiety [13], and psychological distress in the general population [14]. However, no validated measures on the impact of the pandemic on workplaces were available at the time. In this sense, assessing workers' pandemic experiences based on validated measures would have been crucial for providing policymakers, organizations, managers, and leaders with reliable instruments for dealing with the pandemic context and monitoring working conditions, especially for healthcare workers.

For this purpose, Leiter [15] developed the Pandemic Experiences and Perceptions Scale (PEPS), which measures workers' experiences and perceptions of the pandemic. The PEPS is a self-report measure that consists of 34 items across five domains of pandemic experiences and perceptions: (i) disruption, defined as the extent to which the pandemic disrupted workflow; (ii) resources, defined as the extent to which essential resources were available and sufficient to fulfill job demands; (iii) risk perception, defined as the extent to which workers feel at risk and what accounted for their risk perception in terms of contact, control and potential harm; (iv) impact on work-life areas, defined as employees' perceptions of work factors that are predictive of work engagement and burnout: workload, control, reward, community, fairness, and values congruence [15]. Workload refers to work overload where workers «have to do too much in too little time with too few resources» (p. 95) [16], control refers to the degree to which workers perceive that they can influence decisions about their job, work independently, and have access to job resources [16, 17], reward «addresses the extent to which rewards – monetary, social, and intrinsic – are consistent with expectations» (p. 97) [16], community refers to the quality of the workplace social environment, fairness «is the extent to which decisions at work are perceived as being fair and people are treated with respect» (p. 98) [16], and values congruence refers to the congruence between individual and organizational values; (v) perceptions of leadership, defined as leader(s) and immediate manager(s) expressed hope for success and confidence in staff capacity, identified actions that improved capability.

Although some studies have adopted the PEPS [18–29], the psychometric properties of that instrument have not yet been examined.

Understanding workers' pandemic-related perceptions is fundamental to minimizing workers' health and safety risks, so using validated measures is critical for organizations, researchers, and stakeholders. Hence, this study sought to investigate the psychometric properties of the Italian version of the PEPS among Italian hospital workers in the COVID-19 scenario. It examined the internal structure of the scale using confirmatory factor analyses (CFA) and exploratory structural equation modeling (ESEM) techniques and tested the invariance for clinical vs. nonclinical workers.

2. Methods

2.1 Study Design and Participants

A cross-sectional survey was undertaken during a single time frame between April and November 2021 in an Italian hospital. The Limesurvey (https://www.limesurvey.org/it) was used to collect data. Specifically, the survey's link was shared on the hospital intranet. The survey homepage carried the online informed consent form, a clear description of the purpose of the study, and that participation was voluntary and completely anonymous. No sensitive data were requested, and to ensure total anonymity, we did not ask for sex and age in the survey. The

inclusion criteria were: (i) being a hospital worker and (ii) working during the pandemic.

A sample of 1,026 valid questionnaires were collected (response rate 30%). Of those, 253 did not meet the criteria of working during the pandemic and were then deleted. Furthermore, seven were deleted because of missing data in the PEPS items. The final sample comprised 766 hospital workers. Of those, 554 were healthcare workers (i.e., nurses, physicians, and other staff members), and 212 included administrative staff, technicians, and other supporting workers).

2.1.1. Translation and Cultural Adaptation Process

Following the translation/back-translation procedure, we translated the English version of the PEPS into Italian [31, 32]. Initially, two experts independently translated the items into Italian, then back-translated into English by the first author supported by a professional bilingual translator. Finally, a third translator independently compared the original version of the items with the back-translated version to examine and solve any discrepancies.

2.2. Measures

The PEPS is a 35-item self-administered questionnaire divided into six subscales (32 items) and three open-text items measuring sources of help and hope for workers. Precisely, the six subscales measure (i) disruption (3 items; i.e., "To what extent has the pandemic affected the work of your organization?"), (ii) resources (5 items; i.e., "Express your opinion on the adequacy/performance of your protective equipment (e.g., masks, gloves, etc.)"), (iii) risk perception (7 items; i.e., Please indicate how much risk did you perceive to yourself?"), (iv) impact on work-life areas (7 items; i.e., "My work hours were manageable during this period"), and (v) perceptions of leadership concerning the management (5 items; i.e., "The Organizational Management expressed hope for success") and, (vi), direct supervisor (5 items; i.e., "My immediate supervisor expressed hope for success"). PEPS items are scored using a 5-point Likert scale from 1=Not at all/Strongly disagree to 5=Completely/Strongly disagree.

2.3. Statistical Analyses

The factor structure of the Italian version of the PEPS was assessed by comparing five competing models using CFA and ESEM techniques [30]. We considered (i) a unidimensional-CFA model in which all items of the PEPS load on one general factor, (ii) a first-order CFA model where the items of the six dimensions (disruption, resources, risk perception, impact on work-life areas, management leadership, and supervisor leadership) of the PEPS were load on their respective factors, (iii) a second-order CFA where items as the first-order factors accounting for a second-order latent factor, (iv) a model where all items were set to load on their respective factors using ESEM [33], and (v) a second-order ESEM model [33] where a general pandemic experiences and perceptions factor was a function of these six first-order ESEM factors. Our analyses employed a robust maximum-likelihood estimator (MLR) with oblique rotation in Mplus 8.9 [34].

Finally, the final retained measurement model was considered for testing measurement invariance (MI) across occupations (clinical vs nonclinical health care worker). In testing MI, we considered the following steps [35]: configural invariance, metric/weak invariance (invariance of the factor loadings), scalar/strong invariance (loadings and thresholds), strict invariance (loadings, thresholds and uniquenesses), invariance of the latent variances-covariances (loadings, thresholds, uniquenesses and variances-covariances), latent means invariance (loadings, thresholds, uniquenesses, variances-covariances and latent means). The test of configural, metric/weak, scalar/strong, and strict invariances is aimed at assessing measurement biases across the sample, whereas latent variances-covariances and latent means invariances test for meaningful group-based differences at the level of factor variances, covariances, and means.

In assessing model fit, we considered the Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), Root Mean Square Error of Approximation (RMSEA) [36, 37]. For CFI and TLI, values above 0.900 and 0.950 indicate adequate and excellent model fit, respectively. For RMSEA, values lower than .080 and 0.060 indicate adequate and excellent model fit, respectively. In assessing fit improvement

for invariance tests, we used the Mplus DIFFTEST function [38]. We considered the following fit indices [39, 40]: (i) a CFI reduction of 0.010 or less and (ii) an RMSEA increase of 0.015 or less between a model and the preceding model indicates hypothesis rejection for the measurement invariance. Finally, we measured composite reliability for each subscale by calculating ESEM-based McDonald's omega (ω) [41, 42]. As suggested by Morin and colleagues [43], in the ESEM framework, model-based omega coefficients of composite reliability is preferable to the traditional Cronbach's alpha. Values greater than 0.70 are considered to reflect adequate internal reliability.

3. RESULTS

The descriptive statistics of PEPS items are presented in Table 1. As reported in Table 2, the unidimensional-CFA showed an unacceptable level of all goodness-of-fit indices (CFI and TLI≤0.900; RMSEA≥0.080), whereas first-order CFA, H-CFA, and H-ESEM solutions provided an acceptable level of fit according to the CFI (≥0.900) and TLI (≥0.900). The ESEM solution achieved an excellent fit to the data according to the RMSEA (RMSEA≤0.080), supporting the superiority of the six-factor ESEM solution. Parameter estimates associated with these models are reported in Table 3 for the ESEM solution.

3.1. Factor Structure and Reliability

All factors appeared to be globally well-defined overall. Items showed standardized factor loadings (λ=0.10 to 0.97, M=0.71) higher in their *a priori*-defined factor than in the other factors, and low cross-loadings emerged. However, inspecting factor loadings for each factor, one item from the risk perception subdimension showed a low value, item 14 ("Please indicate to what extent did your training, equipment, and support provide you with control over your contact with the virus?"; λ=0.11) and a cross-loading (λ=0.30) on the resources dimension. Concerning factorial intercorrelations and internal consistencies (Table 4), the ESEM-based McDonald's omega (ω) was good for all factors: disruption=0.92, resources=0.86, risk perception=0.83, AWL=0.85, managerial leadership=0.89, direct supervisor leadership=0.94.

Finally, factorial invariance tests across occupational roles (clinical vs. nonclinical hospital workers) were conducted using the six-factor ESEM solution (Table 4).

Table 1. Mean and Standard Deviation (SD) of the PEPS items (N=766).

	Mean	SD
PEPS1	4.18	0.92
PEPS2	4.04	0.98
PEPS3	3.94	1.00
PEPS4	3.22	1.12
PEPS5	3.13	1.05
PEPS6	2.76	1.21
PEPS7	3.13	1.05
PEPS8	2.51	1.14
PEPS9	3.17	0.64
PEPS10	3.11	0.70
PEPS11	3.11	0.67
PEPS12	3.16	0.63
PEPS13	2.47	1.12
PEPS14	3.61	0.84
PEPS15	3.33	1.01
PEPS16	3.37	1.05
PEPS17	3.63	0.94
PEPS18	3.13	0.98
PEPS19	2.99	1.11
PEPS20	3.37	1.02
PEPS21	3.09	1.06
PEPS22	3.44	1.01
PEPS23	2.91	1.05
PEPS24	2.82	1.01
PEPS25	2.90	1.02
PEPS26	2.70	1.09
PEPS27	2.87	1.11
PEPS28	3.17	1.04
PEPS29	3.01	1.11
PEPS30	3.08	1.09
PEPS31	2.90	1.13
PEPS32	3.13	1.13

Table 2. Goodness-of-fit statistics for the estimated models.

Model	χ2	df	CFI	TLI	RMSEA	[90% CI]
M1. Unidimensional-CFA	6759.92	464	0.541	0.509	0.133	[0.130-0.136]
M2. First-order CFA (6 factors)	1497.07	449	0.924	0.916	0.055	[0.052-0.058]
M3. H-CFA	1610.86	457	0.916	0.909	0.057	[0.054-0.060]
M4. Six-factor ESEM	922.04	319	0.956	0.932	0.050	[0.046-0.053]
M5. H-ESEM	1021.05	328	0.949	0.924	0.053	[0.049-0.056]

Note: CFA=confirmatory factor analysis; ESEM=exploratory structural equation modeling; χ2=scaled chi-square test of exact fit; df=degrees of freedom; CFI=comparative fit index; TLI=Tucker-Lewis index; RMSEA=root mean square error of approximation; 90% CI = 90% confidence interval of the RMSEA.

Table 3. Standardized parameter estimates from ESEM.

	Disruption	Resources	Risk Perception	AWL	Management	Supervisor	
	λ1	λ2	λ3	λ4	λ5	λ6	δ
PEPS1	**0.84**	0.02	0.04	0.08	-0.04	-0.03	0.29
PEPS2	**0.97**	-0.02	-0.03	0.00	0.00	-0.04	0.07
PEPS3	**0.83**	-0.03	0.06	-0.03	-0.01	-0.02	0.26
PEPS4	0.08	**0.77**	-0.03	-0.09	-0.02	0.08	0.42
PEPS5	-0.02	**0.85**	-0.02	-0.08	-0.06	0.06	0.35
PEPS6	-0.07	**0.71**	0.07	0.12	0.02	-0.09	0.44
PEPS7	-0.02	**0.68**	-0.02	0.07	-0.06	0.05	0.48
PEPS8	-0.02	**0.51**	-0.05	0.08	0.30	0.00	0.37
PEPS9	-0.02	0.08	**0.91**	-0.01	-0.04	0.03	0.19
PEPS10	-0.02	-0.04	**0.77**	0.08	0.01	-0.04	0.42
PEPS11	-0.06	-0.01	**0.75**	0.05	-0.02	-0.05	0.47
PEPS12	-0.01	0.03	**0.93**	0.04	-0.01	-0.02	0.16
PEPS13	0.22	0.05	**0.27**	-0.22	0.03	0.08	0.77
PEPS14	0.09	0.30	**0.11**	0.14	0.11	-0.03	0.76
PEPS15	0.12	-0.09	**0.45**	-0.12	0.12	0.08	0.71
PEPS16	-0.16	0.05	0.02	**0.49**	0.02	-0.16	0.75
PEPS17	0.03	0.02	-0.08	**0.58**	0.02	-0.08	0.66
PEPS18	0.02	0.01	-0.03	**0.72**	0.06	0.03	0.38
PEPS19	0.00	-0.06	0.01	**0.78**	0.06	0.10	0.29
PEPS20	0.05	0.00	-0.01	**0.62**	-0.05	0.19	0.48
PEPS21	0.01	0.06	0.01	**0.76**	-0.01	0.09	0.30
PEPS22	0.06	0.07	0.00	**0.52**	0.08	0.10	0.53
PEPS23	0.01	0.02	-0.02	-0.10	**0.73**	0.09	0.44
PEPS24	-0.05	0.04	0.04	-0.08	**0.84**	0.03	0.32
PEPS25	0.02	-0.01	0.01	0.04	**0.80**	0.02	0.31
PEPS26	-0.01	0.06	-0.07	0.16	**0.70**	-0.03	0.28

Table 3 (*Continues*)

	Disruption	Resources	Risk Perception	AWL	Management	Supervisor	
	λ1	λ2	λ3	λ4	λ5	λ6	δ
PEPS27	-0.01	-0.03	-0.01	0.09	**0.71**	0.02	0.40
PEPS28	-0.05	0.06	0.01	0.01	0.01	**0.82**	0.26
PEPS29	-0.02	-0.01	0.03	0.00	0.04	**0.89**	0.19
PEPS30	-0.02	0.02	-0.01	0.00	0.04	**0.86**	0.20
PEPS31	-0.01	0.05	-0.05	0.10	0.05	**0.75**	0.20
PEPS32	0.02	-0.01	0.00	0.11	-0.02	**0.81**	0.26

Note: ESEM=exploratory structural equation model; AWL=areas of worklife; λ=standardized factor loading; δ=standardized item uniqueness.

Table 4. Factor correlations and internal consistencies (in diagonal) of the actors for the ESEM solution.

	1	2	3	4	5	6
1. Disruption	(0.92)					
2. Resources	-0.06	(0.86)				
3. Risk Perception	0.37**	-0.26**	(0.83)			
4. Areas of worklife	-0.20**	0.58**	-0.32**	(0.85)		
5. Managerial leadership	-0.09*	0.61**	-0.26**	0.63**	(0.89)	
6. Direct supervisor leadership	0.02	0.49**	-0.17**	0.64**	0.66**	(0.94)

*Note: * p< 0.05; ** 0.01.*

Table 5. Tests of measurement invariance of PEPS across occupational roles.

Model	χ2	df	CFI	TLI	RMSEA	[90% CI]	CM	Δχ2	Δdf	ΔCFI	ΔTLI	ΔRMSEA
Measurement invariance												
M6. Configural invariance	1391.82	638	0.947	0.918	0.056	[0.052-0.060]						
M7. Weak invariance	1548.77	794	0.947	0.934	0.050	[0.046-0.053]	1	170.88	156	0.000	0.016	-0.006
M8. Strong invariance	1597.78	820	0.945	0.934	0.050	[0.046-0.053]	2	48.83	26	-0.002	0.000	0.000
M9. Strict invariance	1608.83	852	0.947	0.938	0.048	[0.045-0.052]	3	28.45	32	0.002	0.004	-0.002
M10. Var-Cov invariance	1656.36	873	0.945	0.937	0.048	[0.045-0.052]	4	47.62	21	-0.002	-0.001	0.000
M11. Latent means invariance	1685.22	879	0.943	0.936	0.049	[0.045-0.052]	5	30.33	6	-0.002	-0.001	0.001

Note: χ2 = scaled chi-square test of exact fit; df = degrees of freedom; CFI = comparative fit index; TLI = Tucker-Lewis index; RMSEA = root mean square error of approximation; 90% CI = 90% confidence interval of the RMSEA; VarCov = variance-covariance; CM = comparison model; Δ = change in fit information relative to the CM.

 p < 0.01.

The configural invariance model adequately fitted the data (CFI=0.947, TLI=0.918, RMSEA=0.056). Then, progressively invariance constraints were added. The weak invariance model (M7; factor loadings constrained equally across groups) fitted the data well (CFI=0.947, TLI=0.934, RMSEA=0.050). The comparison of this model with the configural invariance model (M6) suggested improvement for RMSEA and TLI, revealing equal factor loadings across groups. Then, we tested for the strong invariance model (M8), constraining factor loadings and thresholds to be equal across groups. This model fitted the data well (CFI=0.945, TLI=0.934, RMSEA=0.050), showing the slight change in model fit indices (CFI), then support for the strong measurement invariance. Then, we tested for the strict invariance model (M9), constraining residual variances to be constant across groups. This model fitted the data well (CFI=0.947, TLI=0.938, RMSEA=0.048), showing improved goodness of fit compared with the previous less constrained model (M8).

These results supported the strict invariance of the model. Then, we constrained variances and covariances of all factors to be equal across groups. This model (M10) fitted the data well (CFI=0.945, TLI=0.937, RMSEA=0.048), thus supporting the invariance of the model. Finally, when we tested for the invariance of the latent means across groups, the model (M11) fitted the data well (CFI=0.943, TLI=0.936, RMSEA=0.048), thus supporting the invariance of the model.

4. Discussion

The main aim of our study was to explore the psychometric characteristics of the PEPS in an Italian sample of hospital workers. Specifically, we tested for its factorial structure, internal consistency, and measurement invariance. First, we assessed the factorial validity of the PEPS by contrasting CFA and ESEM solutions. To our knowledge, this study was the first cultural adaptation/validation of the PEPS. In general, our study confirmed the PEPS's multidimensional structure, as Leiter postulated [15] and in line with the literature. For example, in their research, Bailey et al. [21] considered a measurement model in which the PEPS showed an excellent fit to the data. Findings from our study were partially in line with those from Bailey et al. [21], as we showed the superiority of ESEM over traditional restrictive CFA, providing a satisfactory and parsimonious representation of the structure of the PEPS. However, the hypothesized six-factor CFA [15] showed an acceptable fit to the data, suggesting that all the subdimensions of the PEPS are well defined and separated. In this sense, the PEPS is formed by six distinct subdimensions: disruption, resources, risk perception, impact on areas of work life, management leadership, and direct supervisor leadership. Another confirmation of the good psychometric properties of the PEPS is that results from ESEM showed that most of the cross-loadings were below the threshold of 0.30. Only item 14, "Please indicate to what extent did your training, equipment, and support provide you with control over your contact with the virus?" showed moderate cross-loading with the resources subdimension. This may suggest that hospital workers considered training, equipment, and support received as organizational resources. Furthermore, it is possible that workers answered this item considering their adequacy in increasing the control over the virus.

All subscales were good in terms of measure reliability. These results align with previous research, where reliabilities, calculated using Cronbach's alfa, were higher than 0.70 for all PEPS subscales [25, 27].

Finally, an essential contribution of our study was examining measurement invariance models. Measurement invariance tests "the extent to which the content of each [survey] item is being perceived and interpreted in the same way across samples" [44]. In our study, results from the measurement and latent mean invariance tests showed that the ESEM solution was factorially invariant across occupational roles, proving that clinical and nonclinical hospital workers were not different regarding scores of the Italian PEPS constructs. This suggests that the items of the PEPS subscales have the same meanings for clinical and nonclinical hospital workers. This is a significant result, as the PEPS can be reliably used for comparison across professions directly exposed to the pandemic (such as nurses, physicians, etc.)

and those non-directly exposed (such as administrative, technicians, etc.). To the best of our knowledge, this is the first study to investigate the measurement invariance of the PEPS.

4.1. Limitations and Directions for Future Research

The current study has some limitations that need to be acknowledged. First, we employed a cross-sectional research design that precludes any assessment of the test-retest reliability of the PEPS over time. Second, we considered a convenience sample of Italian hospital professionals, limiting the generalizability of our results. Future studies should consider other health professionals working in non-hospital contexts, such as general practitioners, nursing homes, and private hospitals. Third, our results should be interpreted with caution due to a possible selection bias. The 70% of participants who did not respond might have different demographic characteristics, attitudes or experiences with the pandemic. This could lead to nonresponse bias, where the results are influenced by the characteristics of the participants, who may not be representative of the entire population. Finally, we did not assess both convergent and discriminant validity of the PEPS. Future studies should determine the relationship of PEPS with other variables, such as anxiety, stress, etc.

5. Conclusion

Our study explored the structure of the Italian version of the PEPS adopting an ESEM framework, providing evidence of its factorial validity, reliability, and measurement invariance across occupational roles. Despite the limitations highlighted above, the Italian version of the PEPS is a reliable and valid tool for assessing pandemic experiences and perceptions among Italian workers.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the local Independent Ethics Committee (N° Prot PG/2021/5436).

Informed Consent Statement: Participation was voluntary and anonymous. Participants could withdraw from participation in any moment. No sensitive data were requested, and, to ensure total anonymity, we did not ask for sex and age in the survey. Online informed consent was obtained.

Declaration of Interest: The authors declare that they have no competing interests.

Author Contribution Statement: All authors contributed to the study's conception and design. All authors performed material preparation, data collection, and analysis. IP, MG, and MPL wrote the first draft of the manuscript, and all authors commented on previous versions. All authors read and approved the final manuscript.

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