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Development and validation of the North American COmfort of hearing PROtection Device questionnaire (COPROD-NAQ)

Alessia Negrini[a,*], alessia.negrini@irsst.qc.ca, Chantal Gauvin[a], chantal.gauvin@irsst.qc.ca, Djamal Berbiche[b], Djamal.Berbiche@USherbrooke.ca, Jonathan Terroir[c], jonathan.terroir@inrs.fr, Nellie Perrin[c], nellie.perrin@inrs.fr, Caroline Jolly[a], caroline.jolly@irsst.qc.ca, Laurence Martin[d], laurence.martin@umontreal.ca, Franck Sgard[a], franck.sgard@irsst.qc.ca, Olivier Doutres[e], olivier.doutres@etsmtl.ca

[a]Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST), 505 Boul. de Maisonneuve Ouest, Montréal, QC H3A 3C2, Canada

[b]Faculty of Medicine and Health Sciences, Research Center - CSSS Champlain-Charles-Le Moyne, Campus de Longueuil, Université de Sherbrooke, 150 Place Charles-Le Moyne, bureau 200, C.P. 11, Longueuil, QC J4K 0A8, Canada

[c]Institut national de recherche et de sécurité (INRS), 1 Rue du Morvan, 54500 Vandoeuvre-lès-Nancy, France [d]Faculty of Medicine, Université de Montréal, C. P. 6128, succursale Centre-ville, Montréal, QC H3C 3J7, Canada

[e]Department of Mechanical Engineering, École de technologie supérieure (ÉTS), 1100 Rue Notre-Dame Ouest, Montréal, QC H3C 1K3, Canada

[*]Corresponding author at: Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST), 505 Boul. de Maisonneuve Ouest, Montréal, QC H3A 3C2, Canada.

Abstract

The use of hearing protection devices (HPDs), such as earplugs, is essential for mitigating occupational noise-induced hearing loss. However, earplug discomfort often hinders consistent and proper usage. This international and multidisciplinary study is based on a comfort model of HPD use, and considers four comfort dimensions (physical, functional, acoustical, psychological) and the influence of the triad environment/person/earplugs" components on overall comfort. Addressing shortcomings in defining and measuring comfort, the study aims to enrich understanding of the multifaceted aspects of earplug (dis)comfort and the role played by the triad. Specific objectives include developing and validating the "North American COmfort of Hearing PROtection Device Questionnaire (COPROD-NAQ)," proposing a latent overall comfort (LOC) model and comparing earplug families regarding (dis)comfort dimensions. Longitudinal data were collected over a 7-week from 173 workers testing 998 pairs of earplugs in three Canadian manufacturing companies. Factor analyses identified 51 items across 11 conceptual sub-dimensions with satisfactory reliability coefficients. Statistical analyses confirmed the COPROD-NAQ's validity as well. All its sub-dimensions significantly contributed to the LOC, with psychological and functional comfort exerting greater influence. Certain triad component characteristics (e.g., working during weekdays with a day shift, being right-handed, Custom 1 earplug model) enhanced the LOC. Finally, custom earplugs were perceived as most comfortable. The COPROD-NAQ emerges as a powerful tool for assessing earplug comfort and its interaction with triad characteristics, beneficial for occupational health and safety stakeholders. It will aid in prevention programs and help manufacturers design more comfortable earplugs to prevent hearing impairment.

Keywords: Comfort, Earplugs, Work, Questionnaire, Hearing, Prevention

Abbreviations: AD, Acoustical discomfort; *CI*, Comfort index; COPROD-NAQ, North American COmfort of hearing PROtection Device questionnaire; FC, Functional comfort; LOC, Latent overall comfort; PC, Psychological comfort; PD, Physical discomfort; POC, Perceived overall comfort; *SCL*, Specific Comfort Level

1 Introduction

Millions of workers worldwide are exposed to harmful noise, and occupational deafness is one of the most common occupational diseases. For example, in Quebec (Canada), 4.4 % of workers aged 15 years old or more suffer from noise-induced hearing loss (NIHL). This is more common in men, workers aged 65 and over, and those with less than a secondary education level (Camirand et al., 2023). Recent statistics by the Commission des normes, de l'équité, de la santé et de la sécurité du travail showed that around 92% of occupational diseases were related to NIHL (CNESST, 2020). NIHL is a widespread and costly occupational disease. The risk of hearing loss in the workplace depends on both the noise level and the duration of exposure. To prevent this risk, workers often rely on hearing protection devices (HPDs), such as earplugs. These earplugs are a crucial line of defense and one of the most widely used means of protection. They are designed to protect hearing and are generally characterized by their sound attenuation capacity (Berger and Voix 2022). However, ensuring effective protection can be challenging because workers must consistently and correctly wear their earplugs, which are often perceived as uncomfortable (Berger and Voix 2022; Doutres et al. 2019; 2022). Thus, it is essential to recognize that comfort plays a central role in the effectiveness of workers' protection, directly impacting the frequency and quality of earplug use.

1.1 Comfort of earplugs: Definition and measurement

Literature reviews by Doutres et al. (2019; 2020) reveal the complexity surrounding the notion of (dis)comfort related to HPDs (e.g., earplugs) worn by workers, as well as the multiple sources of variability in its assessment from one study to another. To facilitate the selection of the most comfortable earplug model adapted to the user and his/her work environment characteristics, and thus to reduce the barriers of use, Doutres et al. (2020) emphasize the need for a multidimensional approach to describe comfort and highlight the crucial requirement for the rigorous development of a valid measurement questionnaire. Thus, in the context of earplug use, comfort is described through four dimensions (physical, functional, acoustical, psychological) (Doutres et al., 2019). The physical dimension is associated with the mechanical and thermal interactions between the earplug and the earcanal, and related to physical annoyance and pain (e.g., mechanical pressure, irritation or heat felt). The functional dimension covers the practical aspect of earplugs, including ease of use, effectiveness, and utility. The acoustic dimension encompasses the difficult perception of useful sounds (e.g., alarm signals) and their exact localization (e.g., from machines), as well as the occlusion effect leading to unpleasant auditory sensations regarding one's own physiological noises (e.g., altered voice, chewing noise, heartbeat). Lastly, the psychological dimension, rarely addressed in studies devoted to HPDs comfort, concerns the user's well-being and satisfaction (e.g., confidence, habituation). Defining and measuring all these dimensions and their attributes presents a real challenge due to the subjective nature of feelings, opinions, and emotions perceived by earplug users (Davis 2008; Doutres et al., 2019; De Looze et al., 2003; Kolcaba and Kolcaba 1991; Pearson 2009). This subjective experience can carry a negative connotation (i.e., discomfort) that must be operationalized in relation to physical and acoustical dimensions. At the same time, the comfort can also encompass a positive experience for the earplugs' user, which becomes apparent when studying functional and psychological dimensions. In summary, applied to this specific study, the (dis)comfort of earplugs is defined as a global perception characterizing the balance between these four dimensions associated with the relationship between the user and his/her earplugs in the work environment they are worn (definition adapted from Doutres et al., 2019, p 3).

The most common tool employed to collect users' experience with earplugs is the self-reported questionnaire (Doutres et al., 2019). However, measuring an abstract, subjective concept such as (dis)comfort involves several challenges to limit bias due to data collection methods. Although there have been questionnaires developed over the years to measure the comfort of HPDs (Sweetland, 1983; Epps and Casali, 1985; Park and Casali, 1991; Davis and Shaw, 2016), the lack of consensus on the definition of comfort, and consequently on its measurement (Doutres et al., 2019; 2020), leads most studies to assess HPDs comfort based on limited and variable attributes. As reported by Doutres et al. (2019), physical comfort is often measured as the absence of discomfort, the role of the functional attributes on perceived comfort is still ambiguous, and the psychological one is rarely included in the studies. This situation makes (dis)comfort assessment dependent on the premises concerning comfort attributes and complicates the comparison of findings across various studies. Even if few studies consider earplug comfort in a more global context (Arezes et al., 2008; Brown-Rothwell, 1986; Gonçalves et al., 2015; Hsu et al., 2004; Lhuede, 1980), they do not cover all aspects that could influence comfort.. Doutres et al. (2019; 2020) therefore highlight the necessity for a multidimensional approach to understanding comfort in HPDs. In this regard, a recent study validated in France the COPROD (COmfort of hearing PROtection Devices/COnfort des PROtections auDitives) questionnaire capable of assessing the four dimensions of the earplug comfort (Terroir et al., 2021). The results of the study underlined the specific contribution of the functional and psychological dimensions to overall comfort, as well as the role played by some characteristics of the workers (e.g., higher education level) and tested earplugs (e.g., custom). It was a first attempt to measure the multidimensional comfort of the earplugs using a new questionnaire covering a wide range of comfort attributes. Thus, this additional research protocol was needed to improve the understanding of comfort, covering all its dimensions, and identifying the interplay between a wide range of physical and psychosocial characteristics not only of users and earplugs, but also including those of the noisy work environment.

1.2 Triad "Environment/person/earplug"

The earplug (dis)comfort can be influenced by many factors, most of which are currently unknown. According to Doutres et al. (2020), it is recommended to measure as many of these factors as possible and investigate their potential effects on (dis)comfort. Doutres et al. (2020; 2022) divided these factors into three components known as the "triad" (i.e., environment/person/earplug), which are further subdivided into two different categories following their physical and psychosocial characteristics, as originally proposed by Branson and Sweeney (1991). Doutres et al. (2022) include most of these factors (e.g., workplace temperature, worker's age, and earplug shape) and their interactions (e.g., earplug fit quality and attenuation effectiveness) into a holistic model for HPDs, recognizing their potential to significantly influence perceived overall comfort. Despite the importance of the triad components, there have been few field studies that have measured these characteristics, even partially (Terroir et al., 2021). Some other studies have considered how the incompatibility between HPDs characteristics and those of the person (Ivarsson et al., 1990) or of the environment (John et al., 2014) can be related to the discomfort of HPDs. Thus, further exploration is needed to determine which characteristics of the triad influence the comfort of earplugs. As mentioned in Doutres et al. (2022), this knowledge would contribute to improving the proper and consistent use of HPDs through two main strategies: a) aiding in the design of comfortable HPDs for users in their specific work environments and b) implementing interventions (e.g., training, HPD selection) tailored to individuals and their respective work environments.

1.3 Objective

Given the current shortcomings in defining and measuring comfort, as well as understanding the role played by the triad components, this study aimed to enhance the understanding of the multidimensional facets of earplug (dis)comfort, as well as the factors influencing them. To this end, four specific objectives were pursued: 1) to develop a questionnaire tailored to the North American context, titled the "North American COmfort of hearing PROtection Device questionnaire (COPROD-NAQ)", capable of concurrently measuring the earplug comfort and discomfort dimensions, and be easy to use in hearing loss prevention programs or by manufacturers; 2) to validate several psychometric properties of the questionnaire, including content validity, construct validity, internal consistency, test–retest reliability, predictive and divergent validity; 3) to propose a latent overall comfort model assessing the role of each comfort dimension and the characteristics of the triad "environment/person/earplug"; 4) to compare different earplug families on comfort and discomfort dimensions.

2 Methods

2.1 Research protocol and data collection

Longitudinal data were collected over a 7-week period in three Canadian manufacturing companies (N = 173). Companies and participants were recruited based on several eligibility criteria (Table 1).

Table 1

Inclusion and exclusion criteria for companies and participants.

	Inclusion criteria	Exclusion criteria
Company	a) Engaged in indoor work activities. b) Working in a noisy environment requiring the use of HPDs. c) Exposed to non-extreme environmental conditions in terms of humidity and temperature.	a) Engaged in outdoor work activities (e.g., road construction site). b) Exposed to extreme environmental conditions in terms of humidity and temperature.
Participant	a) Aged 18 years or older. b) Able to speak, read, and understand French. c) Aware of the concept of hearing protection.	a) Using dual hearing protection for most working time (i.e., earmuffs and earplugs). b) Having a health issue related to their ears, currently or in the past (e.g., otosclerosis, vertigo). c) Medication treatment in their lifetime (e.g., anxiolytic, chemotherapy). d) Excessive cerumen level not being removed.

As established in the research protocol, workers with hearing loss were allowed to participate. However, for the statistical analyses to be unbiased, this group should have represented between 30 % and 40 % of the total sample.

Nine earplug models were tested. They were carefully chosen from four distinct categories: roll-down foam (three models), premolded (one model), push-to-fit foam (three models), and custom earplugs (two models). The selection process involved a committee of experts. The selected earplugs were diverse, and representative of common models used in Quebec workplaces, as well as extensively in North America. Table 2 summarizes all models used in this study along with their specific noise reduction rating (NRR). The NRR is used in North America to quantify the noise reduction provided by HPDs and is labeled on the packaging.

Table 2

Earplugs families and models tested in the study.

Earplug family	Earplug model		Label used in this study	Noise reduction rating (NRR)
Roll-down foam	3M™ – EAR classic		Cylindrical foam	29 dB
	3M™ – 1100		Bullet shaped foam	29 dB
	Honeywell™ – Howard Leight Max		Bell-shaped foam	33 dB
Premolded	3M™ – Ultrafit		Multi-flange elastomeric polymer	25 dB
Push-to-fit foam	3M™ – SofTouch		Push-to-fit foam sheath	31 dB
	3M™ – Push-ins		Push-to-fit foam pod 1	28 dB
	Honeywell™ – Trust Fit Pod		Push-to-fit foam pod 2	28 dB
Custom	Laboratoire auditif Laviolette		Custom 1	≤ 30 dB
	Custom Protect Ear (dB Blockers™)		Custom 2	26 dB

Table 3 summarizes the main research activities carried out during the data collection process. An example of the testing order followed for the earplug families is presented.

Table 3

Field study research protocol: A synthesis of the data collection process.

Week	Activity and Questionnaire	Earplug family
W0	▪ Group meeting with participants: Presentation of the project and of the information-consent form Individual meeting with participants: Eligibility interview, signature of information-consent form, visual examination of the earcanal, hearing screening and *User Profile Questionnaire* ▪ Earcanal impressions ▪ Collective training of participants: Correctly inserting earplugs	N/A
W1	▪ Individual training ▪ COPROD-NAQ	Roll-down foam
W2	▪ Individual training ▪ COPROD-NAQ	Push-to-fit foam
W3	▪ Individual training ▪ COPROD-NAQ ▪ Participants received the first financial compensation	Premolded
W4	▪ Individual training ▪ COPROD-NAQ	Roll-down foam
W5	▪ Individual training ▪ COPROD-NAQ	Push-to-fit foam
W6	▪ Individual training ▪ COPROD-NAQ	Custom
W7	▪ Individual training ▪ COPROD-NAQ ▪ Participants received the second and last financial compensation	Custom

At the start of the study (W0 in Table 3), during the individual meeting, each participant fulfilled the 47 items of a *User Profile Questionnaire* and answered 7 semi-structured questions, all the 54 items measuring multiple characteristics of the triad (e.g., perceived noise level, work shift, hand dominance, education, tested model and family). Following the comfort model proposed by Doutres et al. (2022), all questions allow for the measurement of numerous physical and psychosocial characteristics of the triad, which are inputs to the model. Thus, their potential influence on the perceived overall comfort can be evaluated. Specifically, the *User Profile Questionnaire* comprised three sections measuring: a) the work environment (30 items; e.g., perceived temperature, work schedule, interpersonal support), b) the person (19 items; e.g., age, prior experience with HPD use, job tenure in the company), and c) the earplug (5 items; e.g., tested model, prior usefulness of the manufacturer's instructions).

During the same individual meeting, participants also underwent an examination of their earcanals conducted by an audiologist. This evaluation included measurements of the earcanal entrance size, otoscopy, and a hearing screening. The results of these assessments were not disclosed to the employer. (Poissenot-Arrigoni et al., 2023).

Environmental conditions (humidity, temperature) and noise levels in the participants' work environments were finally measured at Week 0 (W0 in Table 3) by a member of the research team, without disturbing the workers.

From week 1 to 7 (W1 to W7 in Table 3), each participant received individual training in the proper use of the earplug model to be tested during the week. Typically, he/she tested one earplug randomly selected from each family to compare different earplug models and families. For roll-down foam and push-to-fit foam families, the participant wore the same model of earplugs for one week and then wore it for another week, two weeks apart. For custom earplugs, the participant wore the same model for two consecutive weeks, as this family requires a longer adaptation time (according to information provided by the manufacturers). Moreover, the audiologist performed a fit test in accordance with CSA Z94.2–14 (Canadian Standards Association CSA, 2014), using a field attenuation estimation system (3M™ E-A-Rfit™ Dual-Ear Validation System) to obtain a quantitative measure of the personal noise attenuation provided by the earplug (Poissenot-Arrigoni et al., 2023). This field attenuation estimation system, based on physical measurements using surrogate earplugs, was chosen because it is fast, objective, allows all frequencies to be tested simultaneously, and is not affected by hearing loss (Berger and Voix, 2022). It fits better with this field study research protocol than other methods. For earplug models not compatible with this system, a surrogate model with the closest shape and material was used. This objective fit test enabled the research team to a) verify whether the earplug provided sufficient protection for the participant, b) train the participant to perform a proper fit, and c) estimate the maximum personal attenuation rating (PAR_{80}) of the tested earplug. If both participant's ears failed to achieve a PAR_{80} of 10 dB for all tests where the earplug was inserted by the worker himself, the earplug model was considered unsuitable for the participant's ears and another earplug was randomly selected for the test week, preferably of the same family. If the earplug was deemed suitable for the participant, the research team gave him/her the COPROD-NAQ and a few pairs of earplugs (when disposable). At the end of each test week, the COPROD-NAQ was completed by the participants who expressed their opinions about the four dimensions of earplug comfort. It took approximately 30 min to complete the questionnaire. Their answers were collected using a paper and pencil survey, and then entered online on Snap Surveys 11.31 Professional (Snap Survey s Ltd, 2019).

The following sections outline the methodological steps taken by the research team to develop and validate the COPROD-NAQ.

2.2 Development of the COPROD-NAQ

As part of a broader international study on earplug comfort, the COPROD questionnaire has been developed by the research team and validated first in France (Terroir et al., 2021), and then in North America, which is the subject of this article. Specifically, a multidisciplinary team first worked together to review the literature on the definition and measurement of HPDs comfort (Doutres et al. (2019, 2020)). This allowed to identify existing questionnaires and analyze the dimensions and attributes of earplug comfort. To fulfill the first specific objective of this study, therefore developing the COPROD-NAQ, several steps have been followed. Overall, items derived from existing questionnaires measuring the comfort of earplugs or earmuffs (for more details, see Doutres et al. 2019) were adapted and incorporated into the COPROD-NAQ. If needed, a back translation was carried out by experts in the disciplinary fields and French-English languages. Items were also cross-culturally adapted, considering the specific objectives of the study and the context (e.g., language, legislation, industry, earplug models used in North America). Moreover, new items were added to cover all comfort dimensions and attributes and meet the specific objectives of this research project. Recommendations and references suggested by Corbière and Fraccaroli (2020) were followed for all these steps. The first version of the COPROD-NAQ (v1.0) was composed of 69 items and ready to be validated in North America.

2.3 COPROD-NAQ validation process – Content validity

The first step of the validation process allowed one to test the **content validity** of the COPROD-NAQ (v 1.0) by inspecting the clarity of the items for each dimension and their congruence with the definition of the measured construct (e.g., unambiguous vocabulary accessible to all, logical order of the items, comprehension of the items by the target population) (DeVellis, 2011; Netemeyer et al., 2003). Each comfort dimension is measured with one or two general items representing the dimension, and several explanatory items providing details (i.e., attributes) about the dimension. A group of descriptive items were also included to develop information about a specific attribute (Table 4). On completion of this exercise, the 69 items were divided by the research team into four major conceptual categories: 1) Physical comfort (two general and five explanatory), 2) Functional comfort (one general and 20 explanatory), 3) Acoustical comfort (two general and 12 explanatory), 4) Psychological comfort (two general and 25 explanatory). Most of the responses were rated on a 5-point Likert scale (e.g., from 1 = strongly disagree, to 5 = strongly agree; from 1 = very dissatisfied, to 5 = strongly satisfied).

Table 4

Example of items measuring psychological comfort.

Item		Response scale
General item	33. You feel good when you wear these earplugs	From 1 = strongly disagree, to 5 = strongly agree
Explanatory item	34. You get used to their presence	
Descriptive item	35. You get used to their presence after:	A few seconds, A few minutes, A few hours, A few days

Furthermore, one last item (i.e., *Overall, you would rate this model of earplugs*) was included to measure, on a scale rating from 1 (very poor) to 5 (very good), the perceived overall comfort (POC).

The COPROD-NAQ (v1.0) was then submitted to a group of Canadian experts (e.g., francophone researcher expert in hearing protection from outside the research team, representatives of sector-based workplace associations and experts in occupational noise prevention) to test its content validity and practical properties (e.g., administration duration, ease of use). Following their comments (e.g., to clarify some words to be more understandable to a larger number of participants, to add a temporal adverb to specify the observation period, to add another final question to know the users' preference about the earplugs tested compared to those a participant usually wears at work) the COPROD-NAQ (v2.0) consisting of 61 items accompanied by 15 descriptive items, five open questions, and one final item about overall comfort, was approved by the Research Ethics Committee of the École de technologie supérieure (ÉTS) (#H20171101) and administered to participants.

2.4 COPROD-NAQ validation process – Psychometric properties and data analyses

To meet the second specific objective of the study and respect the notions of validity and reliability, a logical sequence of statistical analyses was followed to validate the COPROD-NAQ. More specifically, Table 5 shows each validation step and the associated analyses carried out. Except for the Confirmatory factor analyses (CFAs) conducted using SAS 9.4 (SAS Institute Inc., 2016), all psychometric properties (i.e., construct validity, internal consistency, test–retest reliability, predictive validity, and divergent validity) and the Exploratory factor analyses (EFAs) were tested using SPSS 28.0 (IBM Corp., 2021).

Table 5

COPROD-NAQ validation steps: Psychometric properties and analyses.

Psychometric property	Statistical analysis
Construct validity	Exploratory factor analyses (EFAs) Confirmatory factor analyses (CFAs) with structural equation modeling (SEM)
Internal consistency	Reliability analysis (Cronbach's alpha)
Test-retest reliability	Intraclass correlation coefficients (ICC)
Predictive validity	Multivariable regression analysis
Divergent validity	Multivariate linear regression analysis

2.4.1 Construct validity

To test the **construct validity**, four **EFAs** were initially performed using SPSS 28.0 to verify the possible presence of conceptual dimensions for each of the four conceptual categories and then to reduce the number of items according to the law of parsimony (Corbière, 2020). First, the non-parametric one-sample Kolmogorov-Smirnov test was carried out to test the normality of the data distribution. Subsequently, the Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) (Thompson, 2004) was assessed, targeting a coefficient of at least 0.60, as recommended by Tabachnick and Fidell (2001). The principal axis factoring (PAF) method with Oblimin rotation was used assuming the correlations between the items for each sub-dimension (Osborne, 2015; Rennie, 1997). Items from the four factorial solutions were retained if their saturation index was at least equal to 0.30 (Netemeyer et al., 2003).

Then, to verify whether the factorial solutions produced by the EFAs fit well with the data, four **confirmatory factor analyses (CFAs)** were performed using SAS software (Netemeyer et al., 2003). Moreover, considering that the COPROD-NAQ is based on assumptions that the dimensions fit into a latent overall comfort variable (LOC), a CFA with structural equation modeling (SEM) was undertaken to test whether the collected data fitted to the hypothesized questionnaire structure. In this study, the model fitted when the following parameters were satisfactory: a) the chi square to degree of freedom ratio ($\chi 2/df$) ≥ 2 (Byrne, 2016; Hofmann, 1995); b) the standardized root mean square residual (SRMR) lower than 0.08 (Hu and Bentler 1999); c) the root mean square error of approximation (RMSEA) between 0.05 and 0.08 (Hu and Bentler 1999; Jöreskog and Sörbom, 1993; Mueller, 1996); d) the comparative fit index (CFI) higher than 0.90. The 90 % Confidence Interval was used to assess the statistical significance of model parameters (Byrne, 2016). Concerning the sample size required for this type of analysis, the threshold set by several authors at a minimum of 200 observations to meet the requirements of the above-mentioned adjustment indices has been respected (Chou and Bentler, 1995; Bollen, 2014). Also, the participant to item ratio was equal to or greater than 5:1 (Gorsuch, 1983; Tabachnick and Fidell, 2001).

2.4.2 Internal consistency

Cronbach's alpha values were then calculated for each final dimension to measure its **internal consistency**, namely, to validate the ability of each set of items to measure a concept (e.g., functional comfort) with a certain degree of homogeneity. Dimensions presenting Cronbach's alphas between 0.70 and 0.95 were considered to have an acceptable internal consistency (DeVellis, 2011).

2.4.3 *Test-retest reliability*

Considering the repeated measures, the intraclass correlation coefficients (ICC) (Trevethan, 2016) were calculated for the **test–retest reliability** with a randomly selected sub-sample and at a 1-week interval (Streiner and Normand, 2008). This specific analysis allows one to assess the stability of COPROD-NAQ determining whether the scores obtained are consistent and stable over time (DeVellis, 2011).

2.4.4 *Predictive validity*

Predictive validity was tested via a multivariable regression analysis. For each component of the triad "environment/person/earplug", the variables were first selected following the existing literature, the variable distributions, and the iterative procedure already used by Poissenot-Arrigoni et al. (2023). Then, to meet the third specific objective of the study, the identified variables (Table 6) were entered in the final model to predict the overall comfort, obtaining robust statistical results which indicate high reliability and validity of the model. All the standardized beta coefficients were interpreted following these criteria: < 0.2 weak association; 0.2–0.5 moderate association; > 0.5 strong association (e.g., Siegel and Wagner, 2022).

Table 6

Independent variables resulting from the iterative procedure of multivariable regression analysis for predictive validity.

Work environment	Person	Earplug
Physical characteristics of the triad* (adapted from Doutres et al., 2022)		
Environmental conditions: Air temperature (cold: yes/no) **Acoustics**: Perceived noise level (1 = very quiet to 5 = very noisy)	**Hand characteristics**: Hand dominance (right-handed, left-handed, ambidextrous)	**Design**: Tested model and family
Psychosocial characteristics of the triad (adapted from Doutres et al., 2022)		
Task and usage: Earplugs interfere with other personal protective equipment (PPE) (yes/no/I don't know), earplugs impede necessary work movements (yes/no/I don't know), working with colleagues (yes/no), work times (weekdays, weekends, variable hours), work shift (day shift, evening-night shift), hours worked per week, exposure time to noise over hours worked per day (%) **Situational influences**: Wearing earplugs because the own workstation generates noise (yes/no), work accommodations to change workstation and/or department (yes/no/I don't know)	**Demographic**: Age categories (21–44 versus 45–65 years old) **Sociocultural**: Education (no degree, secondary or university studies) **Previous experience with earplugs**: Experience with earplug use (from 1 to 37 years; 4 categories (in years): ≤ 5, 6–15, 16–25, ≥26), earplug family and model usually worn at work, duration of earplugs wear per day (minutes, hours, all day long) **Prevention**: Wearing earplugs prevents hearing problems (1 = strongly disagree to 5 = strongly agree)	

For descriptive purposes, an analysis of variance (ANOVA) was conducted to compare the POC among the nine earplug models based on participants' responses to the final question.

2.4.5 *Divergent validity*

Finally, to achieve the four and final specific objective of the study, **divergent validity** of the COPROD-NAQ was estimated via a multivariate linear regression analysis comparing the four families of earplugs on subjective (dis)comfort indices considering the seven weeks of testing. From a statistical perspective, it should be noted that these indices were first calculated as standardized beta (Z scores) with values varying from −1 and + 1, using the formula Standardized $\beta = (x -$

M)/*SD*, where *x* is the raw score, ß the beta, *M* the mean and *SD* the standard deviation. Then, these scores were transformed into t-scores to compare earplug families on standardized scores varying from 0 to 100. Mean standardized (dis)comfort indices were computed for each earplug family and each (dis)comfort sub-dimension.

3 Results

Section 3.1 presents the characteristics of the triad "environment/person/earplug" based on the questions asked by the *User Profile Questionnaire*. The remaining sections illustrate the main results of the statistical analyses carried out following the order of the specific objectives of this study and the validation stages of the COPROD-NAQ.

3.1 Descriptive analyses of the physical and psychosocial characteristics of the triad components

3.1.1 Environment

Three companies operating in the printing, manufacturing, and agri-food sectors, with 200 employees and more, took part in this study. Objective measurements taken in their production areas revealed an average ambient noise level of 86 dB(A), an average temperature of 26 °C (78.8°F) and an average relative humidity of 29 %. It should be noted that the temperature and relative humidity inside the factories could vary depending on the season in which the data were collected. Regarding the subjective perception of the physical conditions of the work environment, participants indicated on a multiple-choice scale that their work environment was mainly hot (87 %) and humid (51 %). Also, about the perceived noise level, on a scale ranging from 1 (very quiet) to 5 (very noisy), they perceived it as noisy (M = 4.30; SD = 0.98). Regarding the main psychosocial characteristics of the work environment, descriptive analyses showed that 88 % of participants were blue collars. Approximately 45 % of respondents indicated that they wear at least two other types of personal protective equipment (PPE) (e.g., mask, glasses) other than earplugs. However, most of them indicated that the earplugs did not interfere with the other PPE worn (85 %) and did not prevent them from making useful movements at work (92 %). Most of the sample declared they worked with colleagues (79 %). Just over half of the participants worked during the normal week (54 %), meanwhile 44 % of them could work during the normal week and the weekend. In terms of work shifts, 57 % of the sample worked during the day, while 43 % worked evening or night shifts. In terms of hours worked per week, the average for the total sample was 42 h (SD = 3.78). Of these hours worked, the participants indicated that they were exposed to noise more than 77 % of the time. Around 60 % of respondents indicated that they wore their earplugs because their workstation generated noise. Results also showed that only a small part of the participants could change workstation (28 %) or the department (22 %) as accommodations to reduce their noise exposure. Around 15 % of them did not know if these accommodations were possible in their company.

3.1.2 Person

The sample consisted of 173 workers. Descriptive analyses showed that most participants were men (87 %). The average age was 46 (SD = 11.13), with over half of the participants aged over 45 (54 %). Most participants had a high school diploma (75 %). Most of them were right-handed (88 %), only two were ambidextrous.

Concerning their work experience, participants have been in the workforce for an average of 26 years (SD = 12.48). They have worked for their current company for an average of 14 years (SD = 11.54) and have held their current position for an average of almost 8 years (SD = 8.06).

The hearing screenings conducted by the audiologist at week 0 revealed that 61 % of the screened participants had normal hearing, while 39 % had a hearing impairment, thus meeting the 40 % threshold set for this study. Among them, 48 % were unilaterally hearing-impaired and 52 % bilaterally hearing-impaired. Of those with hearing loss, the majority (84 %) had a mild loss (26 to 40 dB HL of hearing loss). On average, on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree), respondents agreed that wearing earplugs prevents hearing problems (M = 4.76; SD = 0.62).

Data about their previous experience with earplugs indicated that most of the respondents had been wearing earplugs for an average of 15 years (SD = 9.56). It should be noted that half of the respondents indicated that they had been wearing earplugs for more than 16 years. The most frequently earplug model worn at work was the roll-down foam earplugs (69 %), followed by custom (14 %), push-to-fit foam (12 %), premolded (5 %). In terms of wearing time, three quarters of the sample wore the earplugs all day long.

3.1.3 Earplug

A total of 998 pairs of earplugs were tested during the seven weeks of testing. The frequency of earplug models and families tested is shown in Table 7.

Table 7

Samples of earplug families and models tested in this study.

Tested earplug family n (%)	Tested earplug model n (%)		
Roll-down foam n = 312 (31.5 %)	**Cylindrical foam** n = 125 (13 %)	**Bullet shaped foam** n = 93 (9 %)	**Bell-shaped foam** n = 94 (9.5 %)
Premolded n = 133 (13.5 %)	**Multi-flange elastomeric polymer** n = 133 (13.5 %)		
Push-to-fit foam n = 282 (28 %)	**Push-to-fit foam sheath** n = 93 (9 %)	**Push-to-fit foam pod 1** n = 109 (11 %)	**Push-to-fit foam pod 2** n = 80 (8 %)
Custom n = 271 (27 %)	**Custom 1** n = 121 (12 %)	**Custom 2** n = 150 (15 %)	

Note. N = 998 pairs of earplugs were tested. In this table n refers to the number of the pairs of earplugs tested in the study for each family and model.

3.2 Results of the exploratory and confirmatory factor analyses

Four **EFAs**, one for each comfort dimension, were performed to test the construct validity. For each dimension of comfort, the non-parametric one-sample Kolmogorov-Smirnov test showed that no variable had a normal distribution ($p < 0.001$). Subsequently, the target KMO of at least 0.60 was achieved in each analysis. Following statistical coefficients, 10 items were removed from COPROD-NAQ (v2.0). The results of the EFAs by factoring the principal axes with Oblimin rotation indicated eigenvalues ranging from 1.10 to 9.36. In total, 52 questions spread over 11 factors (conceptual categories) emerged from these four factor analyses (see Appendix A). Then, four **CFAs** were performed to validate this structure. Following the saturation coefficients, a final adjustment was made compared with the structure that emerged from the EFAs. Specifically, for the functional comfort, the item *These earplugs are easy to use* was included in the “Protection from noise” sub-dimension, rather than in the “Insertion” one. For the acoustical discomfort, the item *The noise reduction induced by these earplugs is annoying* was removed from the sub-dimension “External noise”. This adjustment is also consistent from a conceptual point of view. Thus, the final validated version of the COPROD-NAQ (v3.0) is composed of 51 items spread over 11 conceptual sub-dimensions analyzed in EFAs and CFAs. The COPROD-NAQ (v3.0) is also accompanied by seven general and 15 descriptive items, and the final item measuring the POC of the earplugs. To optimize future data collections, open-ended questions are unnecessary, as it has been observed that participants do not provide comments. Tables 8–11 show the final structure of each (dis)comfort sub-dimension of the COPROD-NAQ. CFAs allowed one to compute a factor score for each sub-dimension. This is commonly called “factor” corresponding to a sub-dimension in which a group of items are significantly correlated to each other to measure the same concept. In this specific project, the 11 sub-dimensions that emerged from the factor score equations of the CFA can also be used as subjective (dis)comfort indices. Precisely, each index was obtained by the weighted sum of the Specific Comfort Levels (*SCLs*) that correspond to the average score given to each comfort item by all participants multiplied by their specific Standardized *ß* (Z scores). For each sub-dimension, these tables present the final factorial solution of the COPROD-NAQ, reporting the list of all items along with their number in the questionnaire administered to participants, the keywords representing the measured (dis)comfort attributes, the R-Square coefficients showing the variability of each item, and the related Standardized *ß* (Z scores).

Table 8

The sub-dimension of the physical discomfort (PD)

Item and its related *SCL* label	PD – Physical discomfort *R-Square*	Standardized *ß* *(Z scores)*
5_Pressure ($SCL_{pressure}$)	0.60	0.22
8_Irritation ($SCL_{irritation}$)	0.87	0.32
9_Irritation_Insertion ($SCL_{irritation\_insertion}$)	0.66	0.24
10_Irritation_Wearing ($SCL_{i\_ritation\_wearing}$)	0.80	0.30
11_Irritation_Removal ($SCL_{irritation\_removal}$)	0.72	0.27
Eigenvalue	2.71	
% of total variance	54.14	
Cronbach's alpha	$\alpha = 0.78$	

Table 9

Sub-dimensions of the functional comfort (FC).

Item and its related *SCL* label	FC – Protection from noise *R-Square*	FC – Impact on work *R-Square*	FC – Removal *R-Square*	FC – Insertion *R-Square*	Standardized *ß* *(Z scores)*
16_Effectiveness ($SCL_{effectiveness}$)	0.86				0.93
19_Protection ($SCL_{protection}$)	0.83				0.91
22_Easy_to_Use ($SCL_{ease\_of\_use}$)	0.88				0.94
24_Stay_in_Position ($SCL_{stay\_in\_position}$)	0.57				0.75
20a_Useful_Work_Environment ($SCL_{useful\_work\_environment}$)	0.94				0.97
20b_Useful_Work_Activities ($SCL_{useful\_work\_activities}$)	0.93				0.90
18_Meet_Needs (SCL_{meet_needs})	0.81				0.94
21a_Concentration ($SCL_{concentration}$)		0.94			0.97
21b_Quality_of_Work ($SCL_{quality\_of\_work}$)		0.96			0.98
21c_Productivity ($SCL_{productivity}$)		0.94			0.97
26a_Removal_Easy ($SCL_{removal\_easy}$)			0.94		0.97
26b_Removal_Fast ($SCL_{removal\_fast}$)			0.97		0.98
26c_Removal_Few_Gestures ($SCL_{removal\_few\_gestures}$)			0.72		0.85
23a_Insertion_Intuitive ($SCL_{insertion\_intuitive}$)				0.71	0.85
23b_Insertion_Easy ($SCL_{insertion\_easy}$)				0.92	0.96
23c_Insertion_Fast ($SCL_{insertion\_fast}$)				0.92	0.96
23d_Insertion_Few_Gestures ($SCL_{insertion\_few\_gestures}$)				0.82	0.91
23e_Insertion_Adapted_Work_Pace ($SCL_{insertion\_adapted\_work\_pace}$)				0.92	0.96
Eigenvalue	9.36	2.62	1.67	1.34	
Variance after rotation (cumulative = 79.34%)	50.86	13.60	8.36	6.54	
Cronbach's alpha	$\alpha = 0.93$	$\alpha = 0.96$	$\alpha = 0.94$	$\alpha = 0.94$	

Table 10

Sub-dimensions of the acoustical discomfort (AD).

Item and its related *SCL* label	**AD – External noise** *R-Square*	**AD – Internal noise** *R-Square*	**Standardized** β **(*Z* scores)**
30_Hearing_People_Speaking ($SCL_{hearing\_people\_speaking}$)	0.35		0.59
31a_Hearing_Useful_Sounds ($SCL_{hearing\_useful\_sounds}$)	0.83		0.91
31b_Hearing_Warning_Signals ($SCL_{hearing\_warning\_signals}$)	0.84		0.92
31c_Hearing_Company_Announcements ($SCL_{hearing\_company\_announcements}$)	0.58		0.76
32_Hearing_Localization* ($SCL_{hearing\_localization}$)	0.34		0.58
29a_Annoyance_Own_Voice ($SCL_{annoyance\_own\_voice}$)		0.65	0.81
29b_Annoyance_Chewing ($SCL_{annoyance\_chewing}$)		0.83	0.91
29c_Annoyance_Body_Sounds ($SCL_{annoyance\_body\_sounds}$)		0.79	0.89
Eigenvalue	4.42	1.57	
Variance after rotation (cumulative = 59.65 %)	45.11	14.54	
Cronbach's alpha	$\alpha = 0.84$	$\alpha = 0.90$	

Note. * The original item was recoded to obtain scores going in the same negative direction of the other items in the sub-dimension.

Table 11

Sub-dimensions of the psychological comfort (PC).

Item and its related *SCL* label	**PC – Satisfaction** *R-Square*	**PC – Emotions** *R-Square*	**PC – Immersion** *R-Square*	**PC – Trust/Habituation** *R-Square*	**Standardized** β **(*Z* scores)**
38a_Colour (SCL_{colour})	0.20				0.45
38b_Shape (SCL_{shape})	0.83				0.91
38c_Material ($SCL_{material}$)	0.88				0.94
38d_Roughness ($SCL_{roughness}$)	0.86				0.93
38e_Flexibility ($SCL_{flexibility}$)	0.84				0.92
38g_Insertion ($SCL_{insertion}$)	0.65				0.80
38h_Removal ($SCL_{removal}$)	0.41				0.64
38i_Pressure ($SCL_{pressure}$)	0.81				0.90
38j_Friction ($SCL_{friction}$)	0.86				0.93
37a_Calmness ($SCL_{calmness}$)		0.90			0.95
37b_Ease (SCL_{ease})		0.92			0.96
37c_Relaxation ($SCL_{relaxation}$)		0.90			0.95
37d_Freedom ($SCL_{freedom}$)		0.88			0.94
36_Isolation* ($SCL_{isolation}$)			0.29		0.53
38l_Audibility ($SCL_{audibility}$)			0.93		0.97
38m_Conversation ($SCL_{conversation}$)			0.67		0.82
34_Trust (SCL_{trust})				0.87	0.93
35_Habituation ($SCL_{habituation}$)				0.90	0.95
38f_Staying_in_Position ($SCL_{staying\_in\_position}$)				0.71	0.84
38k_Protection ($SCL_{protection}$)				0.80	0.89
Eigenvalue	9.37	2.27	1.51	1.10	
Variance after rotation (cumulative = 64.84 %)	45.31	10.06	5.64	3.83	
Cronbach's alpha	$\alpha = 0.91$	$\alpha = 0.95$	$\alpha = 0.76$	$\alpha = 0.88$	

Note. * The original item was recoded to obtain scores going in the same positive direction of the other items in the sub-dimension.

For the physical discomfort, only one conceptual sub-dimension emerged, i.e. "PD – Physical discomfort" composed of five items covering pressure and irritation sensations (Table 8).

For illustration purposes, the "PD – Physical discomfort" sub-dimension is here taken as an example. Each item has a *SCL*, as follows $SCL_{Pressure}$, $SCL_{Irritation}$, $SCL_{Irritation\_insertion}$, $SCL_{Irritation\_wearing}$, $SCL_{Irritation\_removal}$, to compute a factor score equation for this sub-dimension, named here subjective comfort index (*CI*) such as

$$CI_{PD-Physicaldiscomfort} = 0.22SCL_{Pressure} + 0.32SCL_{Irritation} + 0.24SCL_{Irritation_{insertion}} + 0.30SCL_{Irritation\_wearing} + 0.27SCL_{Irr} \quad (1)$$

This type of formula can be applied to calculate the other (dis)comfort indices by summing the *SCLs* available in Table 9 to Table 11 when using COPROD-NAQ under conditions like those of this study.

The "PD – Physical discomfort" was correlated with the two general items measuring the general physical annoyance (r = 0.56; $p < 0.001$) and the pain (r = 0.67; $p < 0.001$) generated by the tested models.

The functional comfort (FC) is composed of 18 items spread out on 4 conceptual sub-dimensions: "FC – Protection from noise" (i.e., the effectiveness of earplugs in protecting workers), "FC – Impact on work" (i.e., the impact of wearing earplugs on the concentration, quality of work and productivity), "FC – Removal" (i.e., the ease of removing the earplugs), and "FC – Insertion" (i.e., the ease of insert the earplugs) (Table 9).

The four FC sub-dimensions were significantly correlated with the general item measuring if the tested earplugs were functional (e.g., in terms of efficacy, good maintaining in position, intuitive insertion). The Pearson correlation coefficients varied from 0.36 to 0.83 ($p < 0.001$).

The acoustical discomfort (AD) is composed of eight items spread out on two conceptual sub-dimensions representing the different sources of noise, such as "AD – External noise" and "AD – Internal noise" (Table 10).

The sub-dimension "AD – External noise" was significantly and negatively correlated to both general items measuring if the tested earplugs allowed participants "to hear useful sounds coming from their work environment (e.g., conversations, machines, warning signals, arrival of vehicles)" (r = -0.66; $p < 0.001$) and "not to be annoyed by the sounds coming from their body (e.g., voice, chewing, swallowing, heartbeat, breathing)" (r = -0.61; $p < 0.001$). The sub-dimension "AD – Internal noise" was significantly (and weakly) correlated only to the one measuring the situation "not to be annoyed by the sounds coming from their body" (r = -0.19; $p < 0.001$).

Finally, the psychological comfort (PC) is composed of 20 items distributed across four conceptual sub-dimensions as follows: "PC – Satisfaction" (i.e., satisfaction with the physical characteristics of the earplugs and their use), "PC – Emotions" (i.e., emotions when wearing the earplugs), "PC – Immersion" (i.e., feelings about contextual elements, such as not feeling isolated), and "PC – Trust/Habituation" (i.e., confidence in the earplugs' protection and getting used to their presence) (Table 11).

The sub-dimension "PC – Satisfaction" was positively correlated with the two general items measuring general participants' satisfaction (r = 0.84; $p < 0.001$) and well-being (r = 0.82; $p < 0.001$) when wearing the tested earplugs. The sub-dimension "PC – Trust/Habituation" was negatively correlated with these two general items ($r \leq 0.25$; $p < 0.001$). The sub-dimension "PC – Emotions" was negatively and weakly correlated only to the well-being item (r = -0.07; p = 0.04). Finally, "PC – Immersion" was negatively and weakly correlated only to the satisfaction item (r = -0.07; p = 0.04).

In general, EFAs and CFAs revealed a satisfactory factor structure of the COPROD-NAQ. The total variance explained ranged from 54.14 % to 79.34 % demonstrating a very high level of explained variance, with over 50 % of the variability accounted for in this dataset (Shrestha, 2021; Streiner, 1994). All the Cronbach's alpha coefficients were satisfactory, ranging from 0.76 and 0.96.

Table 12 presents Goodness of fit (GOF) of the CFAs that were carried out for each (dis)comfort dimensions. In general, the results of the CFAs were highly satisfactory since all the Chi square/degree of freedom and RMSEA indices assured the required thresholds for all sub-dimensions. The SRMR values and the CFI were respectively higher (SRMR > 0.08) and lower (CFI < 0.90) than the recommended threshold for the functional and psychological comfort. These values do not undermine the goodness of the model, and are probably due to the sample size, the number of items and sub-dimensions (Kenny and McCoach, 2003; Shi et al. 2019; Xia and Yang, 2019).

Table 12

Fit Summary − Goodness of fit (GOF) of the CFA.

		Physical discomfort (1 sub-dimension)	Functional comfort (4 sub- dimensions)	Acoustical discomfort (2 sub-dimensions)	Psychological comfort (4 sub- dimensions)
Absolute Index	$\chi 2/df$	7.55	4.84	3.67	3.69
	SRMR	0.04	0.13	0.07	0.11
Parsimony Index	RMSEA	0.08	0.06	0.06	0.06
	90 % Confidence Interval	0.06–0.11	0.06–0.07	0.04–0.07	0.05–0.06
Incremental Index	CFI	0.97	0.77	0.91	0.77

When examining the bivariate correlations between the general items and the (dis)comfort sub-dimensions the coefficients *r* turned out not always high or significant. That is probably due to the lack of heterogeneity in the studied variables and because this type of correlation does not consider the impact of other variables in the relationship between the studied variables (Schober et al., 2018).

3.3 Results about the test–retest reliability

The ICC showed that the 11 conceptual sub-dimensions of the COPROD-NAQ can be considered as stable measures at a 1-week time interval. These coefficients are acceptable and fluctuated between 0.12 and 0.50.

3.4 Latent overall comfort model

A further CFA with structural equation modelling confirmed that the data collected with the COPROD-NAQ fitted into a LOC variable in this study.

$$LOC = -0.09*\text{Work Environment\_Cold} + 0.09*\text{Earplugs interfere with other PPE\_No} + 0.11*\text{Work times\_Weekdays} + 0.10*\text{Work shift\_Day shift} + 0.11*\text{Change workstation\_Yes} + 0.13*\text{Change department\_Yes} + 0.08*\text{Hand dominance\_Right-handed} + -0.07*\text{Age} \leq 44 \text{ years old} + 0.32*\text{Earplug Model\_Custom1} + -0.56\, CI_{PD-Physical\ discomfort} + 0.89\, CI_{FC-Protection\ from\ noise} + 0.60\, CI_{FC-Impact\ on\ work} + 0.47\, CI_{FC-Removal} + 0.74\, CI_{FC-Insertion} + -0.28\, CI_{AD-External\ noise} + -0.34\, CI_{AD-Internal\ noise} + 0.91\, CI_{PC-Satisfaction} + 0.64\, CI_{PC-Emotions} + 0.66\, CI_{PC-Immersion} + 0.98\, CI_{PC-Trust/Habituation} \quad (2)$$

Results from a multivariable regression analysis showed that all the 11 sub-dimensions of the (dis)comfort explained the LOC ($p < 0.0001$) (Table 13).

Table 13

(Dis)comfort sub-dimensions explaining the LOC model.

(Dis)comfort sub-dimension	Standardized *β*	*Standard error*	*t*	*p*-value
PD – Physical discomfort	−0.56	0.03	−17.84	<0.0001
FC – Protection from noise	0.89	0.01	114.30	<0.0001
FC – Impact on work	0.60	0.02	28.27	<0.0001
FC – Removal	0.47	0.03	18.37	<0.0001
FC – Insertion	0.74	0.03	48.84	<0.0001
AD – External noise	−0.28	0.03	−8.43	<0.0001
AD – Internal noise	−0.34	0.03	−10.58	<0.0001
PC – Satisfaction	0.91	0.01	136.10	<0.0001
PC – Emotions	0.64	0.02	30.88	<0.0001
PC – Immersion	0.66	0.02	33.31	<0.0001
PC – Trust/Habituation	0.98	0.00	300.70	<0.0001

To test the predictive validity of the COPROD-NAQ on the LOC, each measured component of the triad "environment/person/earplug" (Table 6) was also included in the multivariable regression analysis (Table 14). Three psychosocial characteristics of the work environment positively influenced the comfort, i.e. no interference of earplugs with other PPE, working during weekdays with a day shift, and having the possibility to change position or department. One physical characteristic, i.e. working in a cold environment, decreased the comfort. About person's characteristics, being right-handed increased the overall comfort, while being aged 44 years old or less decreased it. Among the earplug models tested, the Custom 1 favorably contributed to the comfort compared to others.

Table 14

Characteristic of the triad significantly included in the final LOC model.

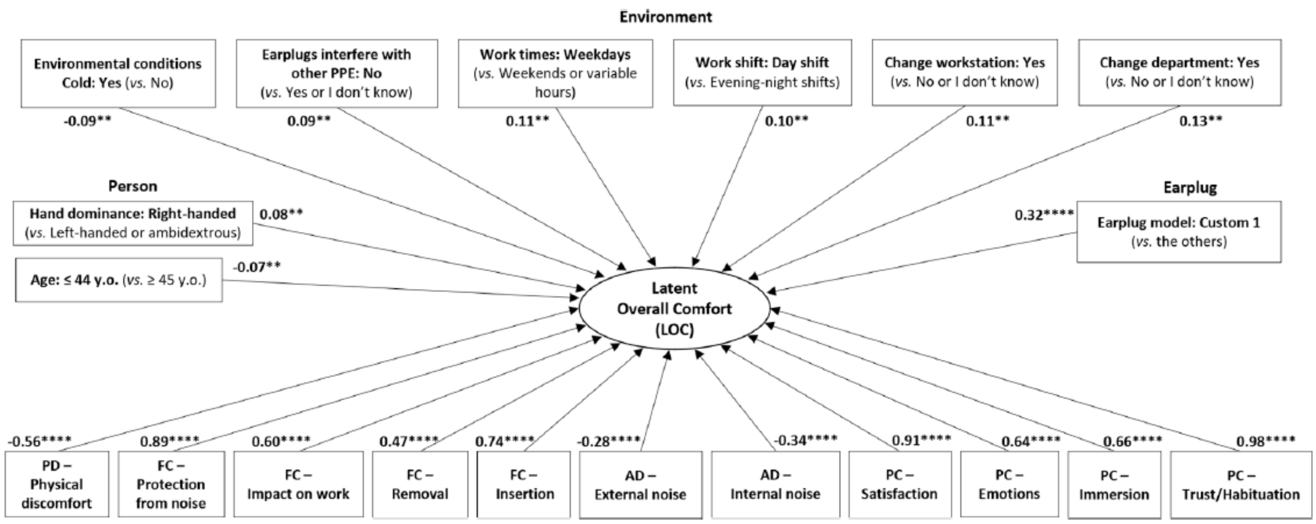
Triad component	Standardized *β*	*Standard error*	*t*	*p*-value
Environment				
Environmental conditions: Cold [Yes (*n*=43; 25.4%)]	**-0.09**	**0.03**	**-2.75**	**0.01**
Acoustics: Perceived noise level	-0.05	0.03	-1.57	0.12
Earplugs interfere with other PPE: No (*n*=129; 85%)	**0.09**	**0.03**	**2.70**	**0.01**
Earplugs impede necessary work movements	0.01	0.03	0.44	0.66
Working with colleagues	-0.01	0.03	-0.15	0.88
Work times: Weekdays (*n*=43; 28%)	**0.11**	**0.03**	**3.34**	**0.00**
Work shift: Day shift (*n*=43; 57%)	**0.10**	**0.03**	**3.10**	**0.00**
Hours worked per week	-0.04	0.03	-1.17	0.24
Exposure time to noise over hours worked per day	-0.03	0.03	-1.03	0.31
Wearing earplugs because the own workstation generates noise: Yes (*n*=99; 59.6%)	0.04	0.03	1.22	0.22
Change workstation: Yes (*n*=43; 28%)	**0.11**	**0.03**	**3.22**	**0.00**
Change department: Yes (*n*=34; 22%)	**0.13**	**0.03**	**3.77**	**0.00**
Person				
Hand dominance: Right-handed (*n*=131; 88%)	**0.08**	**0.03**	**2.41**	**0.02**
Age: ≤ 44 years old (*n*=78; 46%)	**-0.07**	**0.03**	**-2.25**	**0.02**
Education: Secondary studies	0.00	0.03	0.07	0.94
Duration of earplugs wear per day: All day long	-0.02	0.03	-0.45	0.65
Earplug model usually worn at work	0.00	0.03	-0.03	0.98
Earplug family usually worn at work	-0.04	0.03	-1.17	0.24
Wearing earplugs prevents hearing problems	0.05	0.03	1.41	0.16
Earplug				
Tested family: Roll-down foam *vs*. the others (*n*=312; 31.5%)	-0.03	0.03	-1.06	0.29
Tested model: Custom 1 *vs*. the others (*n*=121; 12.1%)	**0.32**	**0.03**	**10.82**	**<.0001**

Note. In bold, all variables significantly related to the LOC.

The final LOC model, including all (dis)comfort sub-dimensions and triad characteristics, is illustrated in Fig. 1.

Fig. 1

Final LOC model



Note. * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$; **** $p < 0.0001$

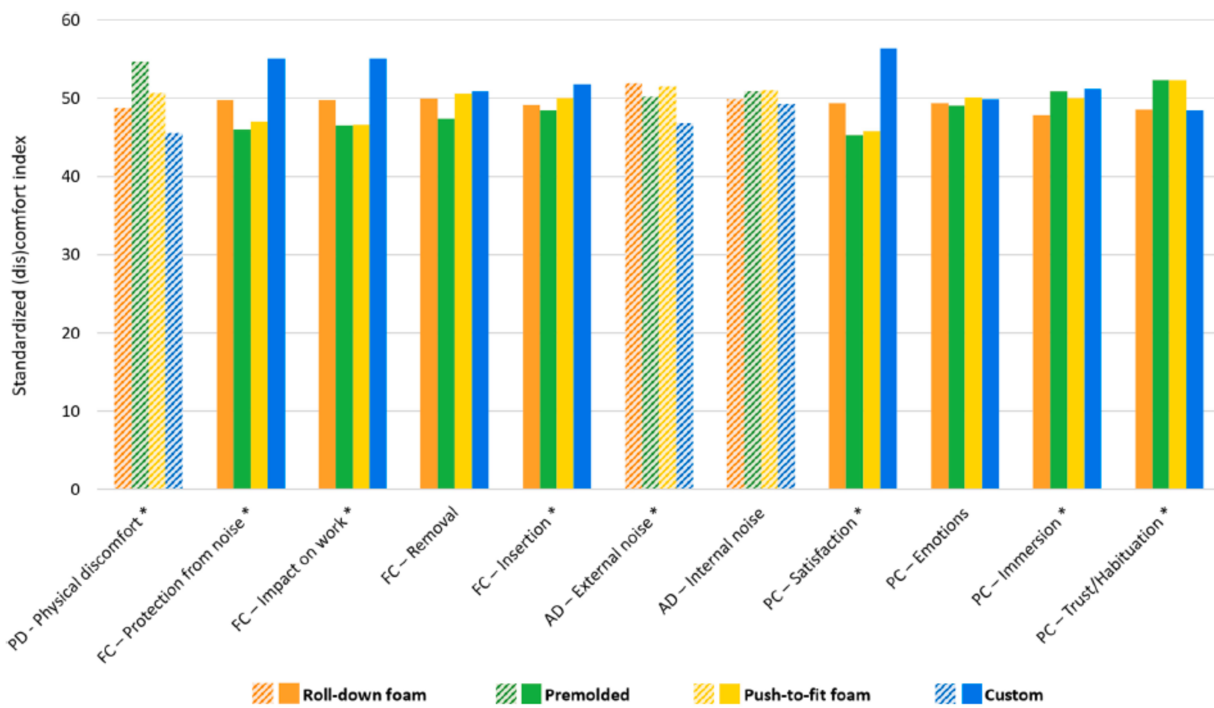
The ANOVA allowed comparing the nine earplug models based on the participants' answers to the final question, which measured the POC. Results revealed significant differences among most of the tested models ($F(8, 882) = 36{,}38$, $p < 0.001$). Specifically, both custom earplug models (Custom 1: $M = 4.26$; $SD = 1.16$; Custom 2: $M = 4.59$; $SD = 0.66$) were perceived as the most comfortable compared to the other tested models. They were followed by two roll-down foam models (Bullet shaped foam: $M = 3.65$; $SD = 1.10$, and Cylindrical foam: $M = 3.60$; $SD = 1.20$, and) that were perceived as more comfortable than other five tested models (similar averages varying from 2.81 to 3.11). As in Terroir et al. (2021) a high correlation was found ($r = 0.93$; $p < 0.0001$) between the POC and LOC variables, confirming the importance of the latent variable for predicting the overall comfort considering all the (dis)comfort dimensions and the triad characteristics included in the final model.

3.5 Divergent validity: Comparing different earplugs families on (dis)comfort

First, mean standardized (dis)comfort indices (t-score values) were computed for each earplug family and each (dis)comfort sub-dimension. Then, multivariate linear regression analysis to compare the earplug families on the 11 subjective (dis)comfort standardized indices were carried out to test the divergent validity of the COPROD-NAQ considering the time perspective of the seven weeks. Results showed that custom earplugs were significantly perceived as the most comfortable ($p < 0.001$). In Fig. 2, it is possible to observe that custom earplugs are significantly and consistently more comfortable than other earplug families on 6 (dis)comfort sub-dimensions. Premolded and push-to-fit foam earplugs were perceived as the least comfortable. Specifically, following each (dis)comfort sub-dimension, custom earplugs are less uncomfortable than other earplug families on the physical dimension (PD – Physical discomfort). Concerning functional comfort, compared to other families, custom earplugs are perceived as more efficient and useful (FC – Protection from noise), having less impact on work through improved concentration, quality of work, and productivity (FC – Impact on work) and easier to insert (FC – Insertion). Roll-down foam earplugs were perceived significantly more comfortable than push-to-fit foam and premolded ones on "FC – Protection from noise". They were also considered more comfortable than push-to-fit foam earplugs on "FC – Impact on work". No differences were found between earplug families regarding the comfort perceived during the removal of the earplugs. About acoustical discomfort, results showed that custom earplugs were perceived to provide less difficulties in hearing useful sounds (AD – External noise). No differences between earplug families in terms of discomforts induced by internal noises were found. Concerning the psychological comfort, custom earplugs were considered by participants significantly and consistently more comfortable than other earplug families on "PC – Satisfaction". Roll-down foam earplugs were perceived by this specific sample significantly more comfortable than push-to-fit foam earplugs and premolded ones on "PC – Satisfaction". Push-to-fit foam earplugs were considered significantly more comfortable than roll-down foam on "PC – Immersion", and significantly more comfortable than custom and roll-down foam ones on "PC – Trust/Habituation". No differences were found between earplug families in terms of emotions.

Fig. 2

Multivariable comparison of the earplug families on subjective (dis)comfort indices.



Note. *F* test: * $p < 0.001$. Solid bars mark the eight sub-dimensions that measure comfort, for which the higher the standardized comfort index, the greater the comfort. Hatched bars mark the three sub-dimensions that measure discomfort, for which the higher the standardized discomfort index, the greater the discomfort.

4 Discussion

To address gaps identified by Doutres et al. (2019; 2020) in the definition and measurement of comfort in HPDs, this international, multidisciplinary study aimed to develop and validate the COPROD-NAQ among a population of workers exposed to noise in North America. To achieve this goal, the research team proposed a model to assess the role of multiple (dis)comfort sub-dimensions and the characteristics of the triad "environment/person/earplug" on the latent overall comfort.

4.1 Quality assessment: Psychometric and practical properties of the COPROD-NAQ

A systematic approach was rigorously followed through various sequential phases to develop and validate this questionnaire. The final version of the COPROD-NAQ comprises 51 items distributed across 11 sub-dimensions (Table 13). It is currently available in French Canadian or American English, the languages spoken by potential respondents in North America. A rigorous process was followed to assess the quality of the questionnaire, via its **psychometric** and **practical properties** (DeVellis and Thorpe, 2021; Diego-Mas et al., 2017; Paulhus and Vazire, 2007). Concerning the **psychometric properties**, multiple levels of analysis were performed to test and confirm the theoretical validity of the COPROD-NAQ and its reliability to measure (dis)comfort of earplugs. According to DeVellis (2011), Cronbach's alpha values indicate that each set of items successfully measure a concept with a certain degree of homogeneity. The ICC demonstrated that COPROD-NAQ can be considered reliable because it remains stable over a short time interval under similar conditions (i.e., wearing the same earplug model) for the same participant.

In general, there are some similarities between COPROD-NAQ conceptual sub-dimensions and those already identified in the previous research conducted in France (Terroir et al., 2021). However, as the research progressed and the questionnaire was adjusted (e.g., items were modified considering their positive and negative direction), the results of the factor analyses carried out for validating the North American version revealed some differences in the questionnaire's structure. For instance, the final analysis of the French COPROD was carried out using only five sub-dimensions corresponding to the structure of the administered questionnaire itself (i.e., Physical_Comfort, Acoustic_Comfort_Perception, Acoustic_Comfort_Occlusion, Functionnal_Comfort, Psychological_Comfort) to make the results easier to interpret. For COPROD-NAQ, the choice was made to retain all the 11 sub-dimensions emerged from the first-order CFA to cover all the facets of the overall comfort. The North American version of the questionnaire allows for measuring discomfort in both the **physical and the acoustical sub-dimensions** using the original items with their negative connotation. In the French study, however, the scores for these two sub-dimensions were recoded into positive values to assess comfort instead. Despite this difference in data processing, both versions of the COPROD confirmed the two sub-dimensions of acoustical (dis)comfort related to internal and external noises (Table 10). Both the North American and French COPROD measured **functional and psychological** comfort dimensions referring to the presence of positive emotions, feelings, attitudes, opinions. This is in line with the assumptions of the theoretical perspective of the Positive Psychology (Seligman and Csikszentmihalyi, 2000) for which well-being is the result of the presence of positive emotions and satisfaction and not the absence of symptoms. Previous studies had conceptualized and measured the "comfort" only as the absence of the discomfort. This questionnaire enables to simultaneously measure the comfort and discomfort of earplugs. Precisely, as mentioned before, the physical and acoustical sub-dimensions have a negative connotation representing discomfort, while the functional and psychological ones have a positive connotation measuring comfort. However, it might be interesting in the future to add a question about the presence of positive attributes, even for the acoustic sub-dimension, as it is known from the literature that wearing protectors by normal-hearing individuals can improve the intelligibility of useful sounds in high noise level environments (Doutres et al., 2020).

Furthermore, factor analyses conducted in North America for functional comfort showed a distribution of items by sub-dimensions that differed slightly from that found in the French study. Specifically, the COPROD-NAQ contains 4 distinct sub-dimensions to measure different facets of functional comfort (Table 9), whereas in the French COPROD some items concerning the earplug removal and insertion are reunited in only one sub-dimension called "Ease of use" (Terroir et al., 2021).

Although the COPROD questionnaires were developed collaboratively by researchers in different countries and yielded similar results, these findings revealed differences between the two versions. These differences can be attributed to several factors. Firstly, during the development and validation process, COPROD underwent cross-cultural adaptation, considering the specific objectives of each project and the context in which the studies were carried out (e.g., country, culture, language, legislation, work environment). Additionally, other differences are related to the research protocols. For instance, in North America, the sample exclusively comprised participants working indoors (without outdoor activities), exposed to continuous, intermittent and/or impact noises (without exposure to impulse noise), and underwent a fit test for each earplug model.

The factorial structure of the COPROD-NAQ, which relies on sets of items maintaining their positive or negative direction, also contributed to recognizing its **practical properties**. Indeed, from a practical perspective, the COPROD-NAQ is simple and not time-consuming to administer. While participants needed approximately 30 min to complete the COPROD-NAQ (v2.0) with 69 items, the validated and simplified version (v3.0) consisting of 51 items should take no longer than 20 min. Compared to the French version, the validated North American questionnaire included more items. For example, a set of explanatory items was added to measure the specific attributes of the users' "satisfaction" in relation to the characteristics of the earplugs (e.g., material) and their use (e.g., fitting), which is one of the main components of the psychological dimension.

The COPROD-NAQ can be hetero or self-administered by the earplug users, and it does not need costly training. To compute the indices of each sub-dimensions of the COPROD-NAQ it is sufficient to follow the formulas given in this paper (i.e., to add up the *SCLs* reported in Table 8 to Table 11) and does not require the support of an expert for result interpretation. Only two items need to be recoded to obtain scores going in the same direction of the other items. They belong to the AD – External noise (i.e., 32_Hearing_Localization) and PC – Immersion (i.e., 36_Isolation) sub-dimensions.

By contacting the corresponding author, the COPROD-NAQ can be made available to several stakeholders (e.g., researchers, professionals, preventionists, students) seeking to administer it to noise-exposed workers using earplugs. It is also accessible to manufacturers aiming, for example, to know the perspective of potential users to design more comfortable earplugs.

4.2 The latent overall comfort

Results showed that all the sub-dimensions explained the latent overall comfort (LOC) (Table 13), confirming the multidimensional nature of the (dis)comfort of the earplugs and the relevance of the proposed structure of this questionnaire. Specifically, psychological, and functional comfort had more weight in explaining the LOC than physical and acoustical discomfort. This finding underlines the importance of considering the comfort attributes related to the practical aspects of the earplugs' use, as well as the user well-being and satisfaction. A similar result was also reported by Terroir et al. (2021) for the French COPROD. Moreover, a hierarchy was observed within each sub-dimension. Concerning psychological comfort, participants' satisfaction with the earplugs (PC – Satisfaction) as well as their confidence and habituation (PC – Trust/habituation) exerted greater influence on the LOC than the emotions experienced when wearing the earplugs (PC – Emotions) and feelings of immersion in their work environment (PC – Immersion). About functional comfort, the sense of being protected by earplugs (FC – Protection from noise) had more weight on the LOC than the ease of insertion (FC – Insertion) which, in turn, had more weight than "FC – Impact on work" and "FC – Removal".

4.3 Effects of the triad on the latent overall comfort

Multiple characteristics of the triad "environment/person/earplug" have been shown to influence altogether the LOC (Fig. 1). Specifically, in the final model, several characteristics of the work environment triad component also stand out: i.e., no interference of earplugs with other type of PPE, working during weekdays with a day shift, having the possibility to change position or department, and working in a cold environment. While modifying user characteristics, such as age, is not feasible, it is possible to make some adjustments to the environment and the earplugs. This finding can inform preventive interventions by suggesting feasible and reasonable modifications. For example, characteristics of the work environment such as work schedule and workstation, and the earplug model, can be adjusted to maintain worker health. However, it is important to note that in this North American sample, only a small number of workers declared they can change the workstation or department. This result was not surprising, as other studies in occupational rehabilitation showed that workstation or organization accommodations refer mainly to the adaptation or change of technical aspects (e.g., height of the worktable), changing work teams with the same employer or rotating tasks (e.g., alternating between two different tasks per day) (Negrini et al., 2020). The least frequently implemented work accommodations are those concerning physical factors (i.e., reducing lighting intensity and noise levels) (Negrini et al., 2018). Job changes are more difficult to achieve in 'more physical' (manual) jobs or in 'heavy' industries (Shaw et al., 2014). However, the results showed how the possibility to change workstation or department can be significantly associated to the comfort of the earplugs when it is combined with the other work environment and person characteristics that emerged as significant in this study. None of the physical or psychosocial characteristics of the work environment emerged as variables significantly associated to the overall comfort in the French study (Terroir et al., 2021).

Regarding the characteristics of the "person" component, hand dominance (i.e., right-handed) and age (i.e., being ≤ 44 years old) impact the overall comfort in North America (Fig. 1). Conversely, in the Terroir et al. (2021), a higher education level and use of the earplugs all day long emerged as determinant factors.

About the characteristics of the third component of the triad, "earplug", the Custom 1 model influenced the overall comfort. From a methodological point of view, the data collected in this study did not allow for a deeper understanding of why this specific custom model influenced significantly overall comfort. One potential explanation that needs further investigation, with more data, is to examine whether variations in comfort between wearing Custom 1 and 2 models depend on specific physical characteristics of custom earplugs (e.g., helix, cords, filters, lubricant). In the French study, although the role played by the earplug models was not measured, it was observed that the custom family had a significant impact on overall comfort.

It is worth noting that the validation process of the COPROD-NAQ included the assessment of the divergent validity, enabling the comparison of (dis)comfort levels of the four earplug families during the 7-week protocol (Fig. 2). In general, participants felt earplugs highly comfortable. It could be hypothesized that the individual training offered to all participants during the fit tests empowered them to wear the earplugs properly, effectively protecting them from noise, moreover, contributing to experiencing comfort rather than discomfort. Additionally, half of the respondents had been using earplugs for more than 16 years, suggesting that a potential habituation effect should have been controlled for. In line with the French findings, this multivariable comparison of earplug families demonstrated in this study that custom earplugs are significantly and consistently more comfortable than other earplug families across all dimensions of comfort. Globally, the earplug families that emerged as the least comfortable were premolded and push-to-fit foam in this North American study, and the roll-down foam in the French one. These differences could be related to the earplug models and families tested in the two studies. This North American study included the push-to-fit foam family (three models), which was not included in the French study, along with only one model in the premolded family, whereas France had three of them. Furthermore, North American participants were not accustomed to wearing the same models at work as French participants: 69 % wore roll-down foam earplugs (compared to 27.1 % in France), and 14 % the custom ones (compared to 58.8 % in France). Finally, the earplugs' testing order was different in the two studies. Thus, the contribution of the custom model (i.e., Custom 1) on the overall comfort does not seem related to the long-term previous experience with earplug model use (Doutres et al., 2020). Finally, the results obtained in the two studies can also be interpreted in the light of certain differences concerning the characteristics of the samples. For example, the North American one consisted of 40 % participants suffering from a unilateral or bilateral hearing loss, compared to 0 % in France. Additionally, a larger proportion of participants in the North American sample reported wearing the earplugs all day long (75 % compared to 46.2 % in France). Furthermore, 57 % of participants perceived their work environment as very noisy, while in France, this rate was lower (25.6 %).

4.4 Strengths, limitations, and the future research perspectives

The COPROD-NAQ is a validated and powerful questionnaire for assessing the multidimensional comfort of earplugs tested, including eight indices measuring functional and psychological comfort and three indices measuring physical and acoustical discomfort starting from workers' subjective experience. Thus, this comprehensive and reliable questionnaire should be capable of capturing all attributes belonging to the multiple dimensions of comfort and quantifying as many of the triad characteristics as possible, using them as covariables.

Following the methods to assess the quality of a tool already adopted by Gragnano et al. (2021), Larivière et al. (2021), and Villotti et al. (2021), it is possible to underline that COPROD-NAQ is an "excellent" questionnaire due to its psychometric (i.e., content validity, construct validity, internal consistency, test–retest reliability, predictive and divergent validity) and practical properties (i.e., administration simplicity and availability in English or French). The administration time and the interpretation of the subjective *CI*s are two characteristics that can be improved in further studies. However, it should be reminded that the current version of COPROD-NAQ allows one to collect a comprehensive portrait of the earplug comfort and discomfort, without redundant items, and the formulas to calculate the subjective *CI*s are presented in this publication. These formulas are not fully generalizable. Although the *SCLs* items used to measure the dimensions of (dis)comfort can be applied in other studies with different samples and work contexts, the coefficients could differ depending on the specific context. A future study could be conducted to statistically compare the coefficients obtained with those from the present study.

Considering the complexity of the research protocol, the participation rate was nonetheless high, even if some of the 173 workers did not complete all seven weeks. Some of them did not answer COPROD-NAQ because they chose to abandon the study, changed jobs without noise exposure, were absent (e.g., for holidays or sick leave), or left the organization for a new job. Research teams withdrawn participants for whom the fit tests were inadequate to protect them from noise during the tests, or because of the arrival of the COVID19 pandemic. The pandemic has presented a challenge in the recruitment process, as barriers to participation have increased significantly. Thus, from week 1 to week 7, the non-response rate was 22 %, which is acceptable in research involving human subjects. Indeed, the sample size for statistical analyses remained adequate, allowing one to achieve the specific objectives of this prospective study, testing the causal relationship between the triad components and (dis)comfort dimensions.

The longitudinal perspective also made it possible to observe whether participants' opinions about the (dis)comfort of earplugs were stable over time, depending on the family tested. Thus, the fact that COPROD-NAQ allowed for measuring (dis)comfort on up to seven occasions enabled a better understanding of participants' feelings regarding their actual working conditions. Despite this strength, it was not possible to account for all organizational and personal changes that may occur. Thus, in future research it would be interesting to consider that the work environment could vary over time. To control it, equipping each participant with a noise dosimeter could be useful to measure physical characteristics of the workstations. Also, wearable tools and mobile technology could make it possible to collect data about participants' physiological parameters and movements when they execute work activities wearing earplugs. Analysis of the participants' work activity would document the variability of working conditions and their impact on the use of earplugs. This could be useful also for the study and the improvement of workers' health.

As reported by Doutres et al., 2020, only few field studies included objective measurements of the environment in their models about HPDs comfort (Arezes and Miguel, 2002; Gonçalves et al. 2015; Sweetland, 1983). Recently, Poissenot-Arrigoni et al. (2023) were able to consider objective measurements of the person, particularly the geometry of the earcanals of workers exposed to noise into real noisy work environments (i.e., physical characteristics of the person). They identified more specifically the characteristics of the triad impacting the physical (dis)comfort.

For the original longitudinal study presented in this publication, the research protocol included a training of workers about earplugs efficient use, through group and individual training with the field attenuation estimation system 3M™ E-A-Rfit™ Dual-Ear Validation System. However, compared to laboratory tests, the recruitment and the follow up with companies and participants were very demanding and expensive (e.g., in terms of human, financial and material resources, and time). Even if it was possible to collect data about real work environments, it was not possible to assess in depth the triad characteristics at each workstation and follow their evolution over time (e.g., temperature, humidity, noise exposure, workload, movements, earplug insertion depth and noise attenuation).

Findings stemmed from this research showed that the validation of the COPROD-NAQ confirmed, as in France (Terroir et al., 2021), the multidimensionality of (dis)comfort, with the contribution of the functional and psychological dimensions, despite differences in research protocols, the characteristics of the triad components, and the adaptation of the questionnaire to the North American context. In addition, attributes that had not been addressed in the previous study (Terroir et al., 2021) have been measured and their contribution to overall comfort has been assessed. Also, it was possible to measure both comfort with its positive attributes and discomfort with its negative attributes in a single study. The emergence of 11 explanatory sub-dimensions of overall comfort allowed expanding the definition of comfort, recognizing the contribution of multiple facets within each dimension. Thus, overall comfort can be defined following a global perception characterized by lower levels of discomfort and higher levels of comfort, considering the specific contribution of the triad components (e.g. age, weekday work, earplug model). More specifically, COPROD-NAQ revealed, on the one hand, the contribution of physical discomfort and internal and external acoustics discomfort, with their negative connotations and, on the other hand, functional comfort (i.e., the effectiveness of earplugs in protecting workers without impacting their work, and ease of insertion and removal) and psychological comfort (i.e., satisfaction, emotions, and feelings of immersion and confidence), with their positive connotations. Added to these findings is the triad's significant role in overall comfort. The *User Profile Questionnaire*, administered in North America, allowed for the consideration of a larger number of variables measuring the characteristics of the triad. This approach helped in going further to understand their interplay that can influence overall comfort. In future applications, COPROD-NAQ should always be accompanied by the *User Profile Questionnaire* (available by contacting the corresponding author). This will help to measure as many triad characteristics as possible to provide data capable of interpreting COPROD-NAQ results considering the target population, organization characteristics, and tested earplugs, as well as to understand the explanatory variables of overall comfort. In terms of semantics and structure of the response scales, COPROD-NAQ is adaptable and usable in other populations, work environments (or laboratories), and earplug models. Future research can contribute to applying the COPROD-NAQ (v3.0) among populations of workers wearing earplugs in various working and cultural environments (e.g., external noise exposure, such as on construction sites) or who speak languages other than French or English. The version validated in this study can be used to measure the comfort to prevent hearing impairment and to design more comfortable earplugs.

5 Conclusion

Considering the lack of consensus in defining comfort and the shortage of validated measurement tools, this study made it possible to develop and validate the COPROD-NAQ enhancing the understanding of the multidimensional aspects of earplug (dis)comfort and its influencing factors. This international research project helped refine the definition of comfort to encompass its various facets and provided a validated tool to measure them rigorously. This COPROD-NAQ allowed for the measurement of the complex multidimensional construct of comfort proposed by Doutres et al. (2019), detailing the process for calculating an index for each dimension as well as an overall comfort index in this specific context. Moreover, the final model identified physical and psychosocial triad characteristics that significantly influenced the overall comfort, demonstrating the potential for promoting earplug comfort by addressing modifiable characteristics of the work environment (e.g., temperature, work schedule) and earplugs model. The variable measuring the family of the tested earplugs, as well as other characteristics of the person (e.g., education) and the environment (e.g., hours worked per week) did not explain the LOC.

Therefore, the assessment of the (dis)comfort and the triad “environment/person/earplug” components can be valuable in hearing loss prevention programs, which can target groups of workers and organizations with specific physical and psychosocial characteristics. By identifying the most important characteristics of the triad components and their impact on comfort, this study provides valuable information for experts in psychology, audiology, ergonomics, as well as engineers and manufacturers. They can refer to these findings and use the COPROD-NAQ with the *User Profile Questionnaire* to collect data supporting the design of more comfortable earplugs tailored to the characteristics of workers and organizations. This should promote a more efficient use of earplugs and reduce hearing loss incidence among workers.

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CRediT authorship contribution statement

Alessia Negrini: Writing – review & editing, Writing – original draft, Validation, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Chantal Gauvin:** Writing – review & editing, Writing – original draft, Methodology, Investigation. **Djamal Berbiche:** Writing – review & editing, Methodology, Formal analysis. **Jonathan Terroir:** Writing – review & editing, Conceptualization. **Nellie Perrin:** Writing – review & editing, Conceptualization. **Caroline Jolly:** Writing – review & editing, Methodology. **Laurence Martin:** Writing – review & editing, Methodology, Investigation. **Franck Sgard:** Writing – review & editing, Project administration, Funding acquisition, Conceptualization. **Olivier Doutres:** Writing – review & editing, Supervision, Project administration, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A

Table A1
Exploratory Factor Analysis: Factor Loadings of items in the subdimension of the physical discomfort (PD).

Item	**PD – Physical discomfort** *R-Square*
5_Pressure	0.60
8_Irritation	0.87
9_Irritation_Insertion	0.66
10_Irritation_Wearing	0.80
11_Irritation_Removal	0.72
Eigenvalue	2.71
% of total variance	54.14
Cronbach's alpha	$\alpha = 0.78$

Table A2
Exploratory Factor Analysis: Factor Loadings of items in the sub-dimension of the functional comfort (FC).

Item	**FC – Protection from noise** *R-Square*	**FC – Impact on work** *R-Square*	**FC – Removal** *R-Square*	**FC – Insertion** *R-Square*
16_Effectiveness	0.88			
19_Protection	0.85			
24_Stay_in_Position	0.70			
20a_Useful_Work_Environment	0.90			
20b_Useful_Work_Activities	0.89			
18_Meet_Needs	0.85			
21a_Concentration		0.89		
21b_Quality_of_Work		0.97		
21c_Productivity		0.96		
26a_Removal_Easy			0.94	
26b_Removal_Fast			0.98	
26c_Removal_Few_Gestures			0.82	
22_Easy_to_Use*				0.85
23a_Insertion_Intuitive				0.82
23b_Insertion_Easy				0.95
23c_Insertion_Fast				0.95
23d_Insertion_Few_Gestures				0.87
23e_Insertion_Adapted_Work_Pace				0.78
Eigenvalue	9.36	2.62	1.67	1.34
Variance after rotation (cumulative = 79.34 %)	50.86	13.60	8.36	6.54
Cronbach's alpha	$\alpha = 0.94$	$\alpha = 0.96$	$\alpha = 0.94$	$\alpha = 0.95$

Note. * After the CFA, the item 22 was included in the "Protection from noise" sub-dimension, rather than in the "Insertion" one.

Table A3

Exploratory Factor Analysis: Factor Loadings of items in the sub-dimension of the acoustical discomfort (AD).

Item	**AD – External noise** *R-Square*	**AD – Internal noise** *R-Square*
30_Hearing_People_Speaking	0.50	
31a_Hearing_Useful_Sounds	0.92	
31b_Hearing_Warning_Signals	0.91	
31c_Hearing_Company_Announcements	0.74	
32_Hearing_Localization*	0.51	
29d_Annoyance_External_Noise_Reduction**	0.45	
29a_Annoyance_Own_Voice		0.82
29b_Annoyance_Chewing		0.88
29c_Annoyance_Body_Sounds		0.87
Eigenvalue	4.42	1.57
Variance after rotation (cumulative = 59.65 %)	45.11	14.54
Cronbach's alpha	$\alpha = 0.83$	$\alpha = 0.90$

Note. * The original item was recoded to obtain scores going in the same negative direction of the other items in the sub-dimension. ** Following the subsequent CFA, the item 29d was not included in the COPROD-NAQ (v3.0).

Table A4

Exploratory Factor Analysis: Factor Loadings of items in the sub-dimension of the psychological comfort (PC).

Item	**PC –Satisfaction** *R-Square*	**PC – Emotions** *R-Square*	**PC – Immersion** *R-Square*	**PC – Trust/Habituation** *R-Square*
38a_Colour	0.42			
38b_Shape	0.79			
38c_Material	0.86			
38d_Roughness	0.85			
38e_Flexibility	0.83			
38g_Insertion	0.68			
38h_Removal	0.59			
38i_Pressure	0.72			
38j_Friction	0.77			
37a_Calmness		0.89		
37b_Ease		0.89		
37c_Relaxation		0.94		
37d_Freedom		0.91		
36_Isolation*			0.52	
38l_Audibility			0.79	
38m_Conversation			0.86	
34_Trust				0.90
35_Habituation				0.70
38f_Staying_in_Position				0.68
38k_Protection				0.81
Eigenvalue	9.37	2.27	1.51	1.10
Variance after rotation (cumulative = 64.84 %)	45.31	10.06	5.64	3.83
Cronbach's alpha	$\alpha = 0.91$	$\alpha = 0.95$	$\alpha = 0.76$	$\alpha = 0.88$

Note. * The original item was recoded to obtain scores going in the same positive direction of the other items in the sub-dimension.

References

Arezes, P. M., Abelenda, C., Braga, A. C. 2008. An Evaluation of Comfort Afforded by Hearing Protection Devices. In: Proceedings of the AHFE 2008—2nd International Conference on Applied Human Factors and Ergonomics, jointly with 12th International Conference on Human Aspects of Advanced Manufacturing (HAAMAHA), 14–17 July, Las Vegas, USA, pp. 1 – 8.

Arezes, P.M., Miguel, A.S., 2002. Hearing protectors acceptability in noisy environments. Ann. Occup. Hyg. 46, 531–536. doi:10.1093/annhyg/mef067.

Berger, E.H., Voix, J., 2022. Hearing Protection Devices. In: Meinke, E.H., Berger, R.L., Neitzel, D.P., Driscoll, Bright, K. (Eds.), The Noise Manual, 6th edition American Industrial Hygiene Association, pp. 255–308.

Bollen, K.A., 2014. Structural equations with latent variables. Wiley, London.

Branson, D.H., Sweeney, M.M., 1991. Conceptualization and measurement of clothing comfort: toward a metatheory. In: Kaiser, Damhorst (Eds.), Critical linkages in textiles and clothing: theory, method and practice. Monument (CO): ITAA Publishers, p p . 94–105.

Brown-Rothwell, D. J., 1986. The Comfort of Earplugs-Basis for a Descriptive Model [master's thesis]. University of Southampton, England.

Byrne, B.M., 2016. Structural Equation Modeling With AMOS: Basic Concepts, Applications, and Programming, Third Edition. 3rd ed. Routledge, New York.

Camirand, H., Conus, F., Davison, A., Dupont, K., Gonzalez-Sicilia, D., Joubert, K., Niyibizi, J., 2023. Enquête québécoise sur la santé de la population 2020-2021. [In French]; Québec, Institut de la statistique du Québec. https://statistique.quebec.ca/fr/fichier/enquete-quebecoise-sante-population-2020-2021.pdf

Canadian Standards Association (CSA), 2014. Hearing Protection Devices -Performance, Selection, Care, and Use. CSA Z94.2-14.

Chou, C.-P., Bentler, P.M., 1995. Estimates and tests in structural equation modelling. In: Hoyle, R.H. (Ed.), Structural Equation Modelling: Concepts, Issues, and Applications. Thousand Oaks, Sage p, pp. 37–55.

Commission des normes, de l'équité, de la santé et de la sécurité du travail (CNESST) 2020. Rapport annuel de gestion 2019. [In French]; Montreal, Canada.

Corbière, M., 2020. Les analyses factorielles exploratoires et confirmatoires: Illustration à l'aide de données recueillies sur l'estime de soi en tant que travailleur. In: Corbière, M., Larivière, N. (Eds.), Méthodes qualitatives, quantitatives et mixtes: dans la recherche en sciences humaines, sociales et de la santé. [In French]; Québec: Presses de l'Université du Québec, pp. 643–674.

Corbière, M., Fraccaroli, F., 2020. La conception, la validation, la traduction et l'adaptation transculturelle d'outils de mesure: des exemples en santé mentale et travail. In: Corbière, M., Larivière, N. (Eds.), Méthodes qualitatives, quantitatives et mixtes: dans la recherche en sciences humaines, sociales et de la santé [In French]; Québec: Presses de l'Université du Québec, pp. 703–752.

Davis, R.R., 2008. What Do We Know about Hearing Protector Comfort? Noise Health 10 (40), 83–89. doi:10.4103/1463-1741.44346.

Davis, R. R. and Shaw, P.B. 2016. "Hearing p rotector comfort and Personal Attenuation Ratings: A real world study. [Communication]." In: Proceedings of the National Hearing Conservation Association. San Diego, CA, USA.

De Looze, M.P., Kuijt-Evers, L.F.M., Van Dieën, J., 2003. Sitting comfort and discomfort and the relationships with objective measures. Ergonomics 46 (10), 985–997. doi:10.1080/0014013031000121977.

DeVellis, R.F., 2011. Scale Development: Theory and Applications. Sage Publications, Thousand Oaks, CA.

DeVellis, R.F., Thorpe, C.T., 2021. Scale Development: Theory and Applications. 5th edition Sage Publications, CA.

Diego-Mas, J.A., Alcaide-Marzal, J., Poveda-Bautista, R., 2017. Errors Using Observational Methods for Ergonomics Assessment in Real Practice. Hum. Factors 59 (8), 1173–1187. doi:10.1177/0018720817723496.

Doutres, O., Sgard, F., Terroir, J., Perrin, N., Jolly, C., Gauvin, C., Negrini, A., 2019. A critical review of the literature on comfort of hearing protection devices: Definition of comfort and identification of its main attributes for earplug ty p es. Int. J. Audiol. 58 (12), 824–833. doi:10.1080/14992027.2019.1646930.

Doutres, O., Sgard, F., Terroir, J., Perrin, N., Jolly, C., Gauvin, C., Negrini, A., 2020. A critical review of the literature on comfort of hearing protection devices: Analy sis of the comfort measurement variability. Int. J. Occup. Saf. Ergon. 28 (1), 447–458. doi:10.1080/10803548.2020.1772546.

Doutres, O., Terroir, J., Jolly, C., Gauvin, C., Martin, L., Negrini, A., 2022. Towards a holistic model explaining hearing protection device use among workers. Int. J. Environ. Res. Public Health 19 (9), 1–20 5578 doi:10.3390/ijerph19095578.

Epps, B.W., Casali, J.G., 1985. Hearing Protection Device Comfort and User Preference: An Investigation and Evaluation Methodology. In: Proceedings of the Human Factors Society Annual Meeting 29 (8), 814–818. doi:10.1177/154193128502900821.

Gonçalves, C.G.O., Lüders, D., Guirado, D.S., et al., 2015. Perception of hearing protectors by workers that participate in hearing preservation programs: A preliminary study. CoDAS 27 (4), 309–318. doi:10.1590/2317-1782/20152014139.

Gorsuch, R.L., 1983. Factor Analy sis, 2nd edition Psy chology Press. doi:10.4324/9780203781098.

Gragnano, A., Villotti, P., Larivière, C., Negrini, A., Corbière, M., 2021. A systematic search and review of questionnaires measuring individual psychosocial factors predicting return to work after musculoskeletal and common mental disorders. J. Occup. Rehabil. 31, 491–511. doi:10.1007/s10926-020-09935-6.

Hofmann, R., 1995. Establishing factor validity using variable reduction in confirmatory factor analysis. Educ. Psychol. Meas. 55 (4), 572–582. doi:10.1177/0013164495055004O.

Hsu, Y.-L., Huang, C.-C., Yo, C.-Y., Chen, C.-J., Lien, C.-M., 2004. Comfort Evaluation of Hearing Protection. Int. J. Ind. Ergon 33 (6), 543–551. doi:10.1016/j.ergon.2004.01.001.

Hu, L.-T., Bentler, P.M., 1999. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. Struct. Equ. Model. 6 (1), 1–55. doi:10.1080/10705519909540118.

IBM Corp. Released 2021. IBM SPSS Statistics for Windows (Version 28.0) [Software]. Armonk, NY: IBM Corp.

Ivarsson, A., Toremalm, N.G., Brühl, P., 1990. Eczema, Itching, Heat and Humidity Problems- Impediments to the Effective Use of Hearing Protectors. Proceedings of the Internoise 1990 90, 1093–1096.

John, G.W., Grynevych, A., Welch, D., McBride, D., Thorne, P.R., 2014. Noise Exposure of Workers and the Use of Hearing Protection Equipment in New Zealand. Arch. Environ. Occup. Health 69, 69–80. doi:10.1080/19338244.2012.732122.

Jöreskog, K.G., Sörbom, D., 1993. LISREL 8: Structural equation modelling with the SIMPLIS command language. Lawrence Erlbaum Associates Inc, Scientific Software International.

Kenny, D.A., McCoach, D.B., 2003. Effect of the number of variables on measures of fit in structural equation modelling. Struct. Equ. Model. Multidiscip. J. 10 (3), 333–351. doi:10.1207/S15328007SEM1003_1.

Kolcaba, K.Y., Kolcaba, R.J., 1991. An Analysis of the Concept of Comfort. J. Adv. Nurs. 16 (11), 1301–1310. doi:10.1111/j.1365-2648.1991.tb01558.x.

Lhuede, E. P., 1980. Ear Muff Acceptance among Sawmill Workers. Ergonomics 23 (12), 1161–1172. doi:10.1080/00140138008924823.

Negrini, A., Corbière, M., Lecomte, T., Coutu, M.-F., Nieuwenhuijsen, K., St-Arnaud, L., Berbiche, D., 2018. How can supervisors contribute to the return to work of employees who have experienced depression? J. Occup. Rehabil. 28 (2), 279–288. doi:10.1007/s10926-017-9715-0.

Larivière, C., Nastasia, I., Corbière, M., Truchon, M., Côté, D., Mathieu, A., Dionne, C., Gragnano, A., Villotti, P., Negrini, A., Bussières, A., Busque, M.-A., Lebeau, M., Coutu, M.-F. (2021). Élaboration du contenu d'un site web portant sur l'incapacité et le retour au travail. Rap p ort R-1083-fr, Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST). [In French] Montreal, 89pp.

Negrini, A., Corbière, M., Dubé, J., Gragnano, A., Busque, M-A., Lebeau, M., Brondino, M., Vila Masse, S. 2020. Quels sont les déterminants du retour au travail durable des travailleurs seniors ayant subi une lésion psychologique ou physique? Rapport R-1116, Institut de recherche Robert Sauvé en santé et en sécurité du travail (IRSST). [In French] Montreal, 86pp.

Netemeyer, R.G., Bearden, W.O., Sharma, S., 2003. Scaling Procedures: Issues and Applications. Sage Publications, Thousand Oaks, CA. https://doi.org/10.4135/9781412985772.

Osborne, J.W., 2015. What is Rotating in Exploratory Factor Analysis? Pract. Assess. Res. Eval. 20 (2), 1–7. doi:10.7275/hb2g-m060.

Park, M.-Y., Casali, J.G., 1991. An Empirical Study of Comfort Afforded by Various Hearing Protection Devices: Laboratory versus Field Results. Appl. Acoust. 34 (3), 151–179. doi:10.1016/0003-682X(91)90082-P.

Paulhus, D.L., Vazire, S., 2007. The self-report method. In: Robins, R.W., Fraley, R.C., Krueger, R.F. (Eds.), Handbook of Research Methods in Personality Psychology. The Guilford Press, pp. 224–239.

Pearson, E.J.M., 2009. Comfort and Its Measurement–A Literature Review. Disabil. Rehabil. Assist. Technol. 4 (5), 301–310. doi:10.1080/17483100902980950.

Poissenot-Arrigoni, B., Negrini, A., Berbiche, D., Sgard, F., Doutres, O., 2023. Analysis of the physical discomfort of earplugs experienced by a group of workers in Canadian companies and identification of the influencing variables. Int. J. Ind. Ergon. 98, 1–16. doi:10.1016/j.ergon.2023.103508.

Rennie, K.M., 1997. Exploratory and Confirmatory Rotation Strategies in Exploratory Factor Analysis. Educational Research Association, Austin, TX, USA.

SAS Institute Inc, 2016. SAS® 9.4 Language Reference: Concepts. Sixth Edition SAS Institute Inc., Cary, NC.

Schober, P., Boer, C., Schwarte, L., 2018. Correlation Coefficients: Appropriate Use and Interpretation. Anesth. Analg. 126 (5), 17630. doi:10.1213/ANE.0000000000002864.

Seligman, M.E., Csikszentmihalyi, M., 2000. Positive psychology. An introduction. Am. Psychol. 55 (1), 5–14. doi:10.1037/0003-066X.55.1.5.

Shaw, W.S., Kristman, V.L., Williams-Whitt, K., Soklaridis, S., Huang, Y.-H., Côté, P., Loisel, P., 2014. The job accommodation scale (JAS): Psychometric evaluation of a new measure of employer support for temporary job modifications. J. Occup. Rehabil. 24 (4), 755–765. doi:10.1007/s10926-014-9508-7.

Shi, D., Lee, T., Maydeu-Olivares, A., 2019. Understanding the Model Size Effect on SEM Fit Indices. Educ. Psychol. Meas. 79 (2), 310–334. doi:10.1177/0013164418783530.

Shrestha, N., 2021. Factor Analysis as a Tool for Survey Analysis. Am. J. Appl. Math. Stat. 9 (1), 4–11. doi:10.12691/ajams-9-1-2. 1.

Siegel, A. F., Wagner, M. R., 2022. Practical Business Statistics, Eighth Edition Elsevier Inc. doi:10.1016/C2019-0-00330-5.

Streiner, D.L., 1994. Figuring out factors: The use and misuse of factor analysis. Can. J. Psychiatry 39 (3), 135–140. doi:10.1177/070674379403900303.

Streiner, D.L., Normand, G.R., 2008. Health measurement scales: A practical guide to their development and use. 4th edition Oxford University Press, Oxford.

Snap Surveys, 2019. Snap 11 Professional (Build 11.31) [Software]. Snap Surveys Ltd, Bristol, UK.

Sweetland, K.F., 1983. Physical predictors for earmuff comfort [master's thesis]. Loughborough University of Technology, Lougborough.

Tabachnick, B.G., Fidell, L.S., 2001. Using Multivariate Statistics. 4th edition Allyn and Bacon, Boston, MA.

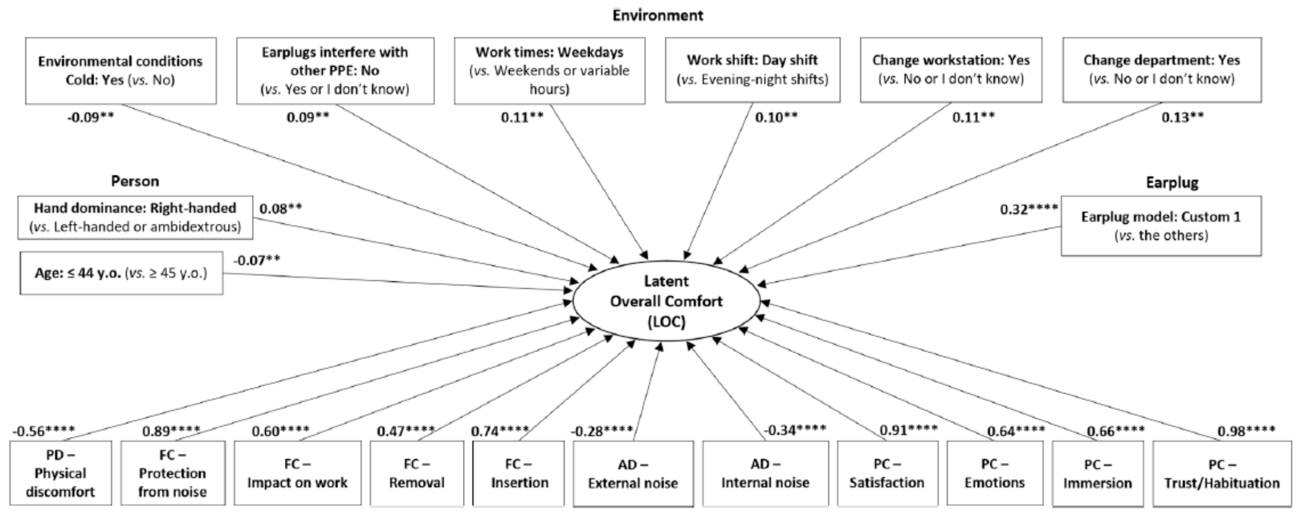
Terroir, J., Perrin, N., Wild, P., Doutres, O., Sgard, F., Gauvin, C., Negrini, A., 2021. Assessing the comfort of earplugs: Development and validation of the French version of the COPROD questionnaire. Ergonomics 64 (7), 912–925. doi:10.1080/00140139.2021.1880027.

Trevethan, R., 2016. Intraclass correlation coefficients: Clearing the air, extending some cautions, and making some requests. Health Serv. Outcomes Res. Method. 17, 127–143. doi:10.1007/s10742-016-0156-6.

Villotti, P., Gragnano, A., Larivière, C., Negrini, A., Dionne, C.E., Corbière, M., 2021. Tools appraisal of organizational factors associated with return-to-work in workers on sick leave due to musculoskeletal and common mental disorders: A systematic search and review. J. Occup. Rehabil. 31 (1), 7–25. doi:10.1007/s10926-020-09902-1.

Xia, Y., Yang, Y., 2019. RMSEA, CFI, and TLI in structural equation modelling with ordered categorical data: The story they tell depends on the estimation methods. Behav. Res. Methods 51, 409–428. doi:10.3758/s13428-018-1055-2.

Graphical abstract



Highlights

- COPROD-NAQ questionnaire assesses the multidimensional (dis)comfort of earplugs.
- Custom earplugs are generally perceived as more comfortable.
- Triad "environment/person/earplugs" influence the overall comfort.
- Development of a comfort index for earplugs to improve workers' hearing protection.