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WHO Environmental Noise Guidelines for the European Region: A Systematic Review on Environmental Noise and Permanent Hearing Loss and Tinnitus

Mariola Śliwińska-Kowalska 1,* and Kamil Zaborowski²

1. Inclusion and Exclusion Criteria for Individual Studies

Table S1. Individual studies had to meet the following criteria in order to be included in the evidence review. If the criteria were adjusted, a justification is given detailing the reasons.

	Inclusion Criteria	Exclusion Criteria
Population : general population in settings (hospitals, residences, public venues, educational facilities)	 Studies including members of the general population Studies including specific segments of the population particularly at risk, such as children or vulnerable groups Studies including participants exposed to noise in occupational settings if relevant with combined exposure to environmental noise only 	 Does not meet inclusion criteria Studies including participants exposed to noise in occupational settings not relevant with combined exposure to environmental noise
Exposure : exposure to high levels of environmental noise from various noise sources	- Noise exposure levels either measured or calculated and expressed in decibel values. They should aim to be representative of the individual exposure of the study participants.	 Does not meet inclusion criteria Studies using hearing loss or defective hearing as a proxy for (previous) noise exposure Surveys assessing noise exposure on the basis of subjective ratings, as given by the subjects in a questionnaire
Comparator : no noise exposure or lower levels of noise exposure	- Should have comparator group (corresponding to no exposure or lower level exposure)	- Does not meet inclusion criteria
Confounding : adjusted for confounding	- No inclusion criteria applied; however, for every study, we will assess which possible confounders have been taken into account	- No exclusion criteria applied
Outcome : assessment of outcome	 Permanent threshold shift measured with pure-tone audiometry and permanent tinnitus assessed with the questionnaire; Relative risks (RR) or odds ratios (OR) as primary outcome measures 	- Does not meet inclusion criteria

Risk of Bias Check List for Studies on Noise and Health Outcomes	Study Name:	Assessor Name:	Date Assessed:
	Cohort		
Study Design	Case-control		
	Cross-sectional		
Domain	Description of criteria for judgment	Quote from article on which the judgment is based	Judgment of risk of bias
Noise Exposure assessment leading to information bias			
	 The noise level (in decibel) is expressed in Lden and Lnight or its components (Lday, Levening, Lnight and the duration in hours of Lnight) AND: For long term average noise level: A. is based on a noise map using as input the actual traffic volume, composition and speed per 24 h per road/railway /airport, or the type and sound power of an industrial installation and the size in terms of either production volume or persons employed OR B. is based on measurements for a minimum of 1 week by qualified staff, and adjusted for data under point A. as well as meteorological conditions when necessary OR C. is based on a noise map reported in a separate publication but which fulfils conditions A or B For short-term noise level: D. is based on measurements for a sufficient time by qualified staff The noise level is not expressed in decibels OR is not expressed in Lden and Lnight or its 		Low
	 components OR: For long term average noise level: A. is based on a map that does not use as input the actual traffic volume, composition and speed per 24 h per road/railway/airport, or the type and sound power of an industrial installation and the size in terms of either production volume or persons employed OR B. is based on measurements of less than 1 week OR not adjusted for data under point A. or meteorological conditions when necessary OR by unqualified staff OR C. is based on a noise map reported in a separate publication but which does not fulfils conditions A or B For short-term noise level: D. is based on measurements for an insufficient time OR by unqualified staff If not enough information reported, to judge the above 		High Unclear

Table S2. The template for assessment of quality and risk of bias.

Bias due to contounding

At least the following confounders should be incorporated for a valid assessment for the relation between noise and XXX outcome: 1234	All important confounders taken into account either through matching, restriction or in the analysis	Low
	Only 1 or no confounder taken into account OR Subjects in exposed and unexposed groups differ for one or more important confounders and there is no adjustment in the analysis	High
	Less then all to >1 important confounders taken into account OR Insufficient information to decide on one of the above	Unclear
Bias due to selection of Participants		
	Participants randomly sampled from a known population AND response rate higher than 60% AND attrition rate less than 20% in follow up studies	Low
	No random sampling OR response rate less than 60%	High
	No information to judge the above	Unclear
Health outcome assessment leading to information bias	I	
	The health outcome of interest is objectively measured OR taken from medical records OR	Low
	taken from questionnaire or interview using a known scale or validated assessment method	LOW
	The health outcome of interest is self-reported and not assessed using a known scale or validated assessment method	High
	Not sufficient information reported to assess the above	Unclear
Health outcome assessment leading to information bias	П	
	The health outcome of interest is assessed blind for exposure information in cohort and cross-	Low
	sectional studies or exposure is assessed blind for being a case in case-control studies	LOW
	The health outcome and/or exposure assessment is not blinded	High
	Not sufficient information reported to assess the above	Unclear
	Total Risk of Bias in Study	
	At least 4/5 at low risk of bias, including for domains 1, 2 and 3	Low
	Any other	High

Table S3. GRADE for quality of evidence from personal listening devices associated with hearing impairment and tinnitus.

	Hearing Impairment				
Domains	Criterion	Assessment	Downgrading		
Start Level	Longitudinal = high; others = low	All cross-sectional studies	Low quality		
1. Study Limitations	Majority of studies low quality	All with high risk of bias	Downgrade one level		
2. Inconsistency	Conflicting results; high I ²	Generally consistent results on association between environmental noise and permanent hearing loss	No reason for downgrading		
3. Directness	Direct comparison; same PECO*	Yes, same PECO*	No reason for downgrading		
4. Precision	Confidence interval contains 25% harm or benefit	All CI wider than 25%	Downgrade one level		
5. Publication Bias Overall judgment	Funnel plot indicates	Not able to assess; too few studies	No downgrade Verv low quality		
6. Exposure-response	Significant trend	Not observed	No upgrading		
7. Magnitude of effect	RR > 2	Not observed	No upgrading		
8. Confounding adjusted	Effect in spite of confounding working towards the nil	Not observed	No upgrading		
Overall Judgement			Very low quality		
	Tinı	nitus			
Domains Criterion Assessment Downgrading					
Start Level	Longitudinal = high; others =	A 11	0 0		
	low	All cross-sectional	Low quality		
1. Study Limitations	low Majority of studies low quality	All cross-sectional All studies with high risk of bias	Low quality Downgrade one level		
 Study Limitations Inconsistency 	low Majority of studies low quality Conflicting results; high I²	All cross-sectional All studies with high risk of bias Contradictory results on association between environmental noise and permanent tinnitus	Low quality Downgrade one level Downgrade one level		
 Study Limitations Inconsistency Directness 	low Majority of studies low quality Conflicting results; high I ² Direct comparison; same PECO*	All cross-sectional All studies with high risk of bias Contradictory results on association between environmental noise and permanent tinnitus Yes, same PECO*	Low quality Downgrade one level Downgrade one level No reason for downgrading		
 Study Limitations Inconsistency Directness Precision 	low Majority of studies low quality Conflicting results; high I ² Direct comparison; same PECO [*] Confidence interval contains 25% harm or benefit	All cross-sectional All studies with high risk of bias Contradictory results on association between environmental noise and permanent tinnitus Yes, same PECO* All CI wider than 25%	Low quality Downgrade one level Downgrade one level No reason for downgrading Downgrade one level		
 Study Limitations Inconsistency Directness Precision Publication Bias 	low Majority of studies low quality Conflicting results; high I ² Direct comparison; same PECO* Confidence interval contains 25% harm or benefit Funnel plot indicates	All cross-sectional All studies with high risk of bias Contradictory results on association between environmental noise and permanent tinnitus Yes, same PECO [*] All CI wider than 25% Not able to assess	Low quality Downgrade one level Downgrade one level No reason for downgrading Downgrade one level No reason for downgrading		
 Study Limitations Inconsistency Directness Precision Publication Bias Overall judgment 	low Majority of studies low quality Conflicting results; high I ² Direct comparison; same PECO* Confidence interval contains 25% harm or benefit Funnel plot indicates	All cross-sectional All studies with high risk of bias Contradictory results on association between environmental noise and permanent tinnitus Yes, same PECO [*] All CI wider than 25% Not able to assess	Low quality Downgrade one level Downgrade one level No reason for downgrading Downgrade one level No reason for downgrading Very low quality		
 Study Limitations Inconsistency Directness Precision Publication Bias Overall judgment Exposure-response 	low Majority of studies low quality Conflicting results; high I ² Direct comparison; same PECO* Confidence interval contains 25% harm or benefit Funnel plot indicates Significant trend	All cross-sectional All studies with high risk of bias Contradictory results on association between environmental noise and permanent tinnitus Yes, same PECO* All CI wider than 25% Not able to assess Not possible to assess	Low quality Downgrade one level Downgrade one level No reason for downgrading Downgrade one level No reason for downgrading Very low quality No reason for upgrading		
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* Population Exposure Comparator Outcome.

Risk of Bias Check List for Studies on Noise and Health Autometric Thresholds and Portable Digital Audio Player User Habits. Assessor Name: Mariola Silvinka-Kowalaka Kamil Zaborowski Date Assessed: Mariola Silvinka-		REFERENCE No 1		
Studies on Noise and Health Audiometric Thresholds and Portable Digital Audio Player User Habris. Mariola Sliwinska-Kowalska, Kamil Zaborowski, Kamil Zaborowski, Kamil Zaborowski, Kamil Zaborowski, Kamil Zaborowski, Kamil Zaborowski, Study Design Date Assesse: Comparison of Criteria for judgment of Cross-acchional in	Risk of Bias Check List for	Study Name: Assessor Name:		
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Domain Description of criteria for judgment Judgment of risk of bias	Study Design	<u>Cross-sectional</u>		
Noise Exposure assessment leading to information bias	Domain	Description of criteria for judgment	Judgment of	
		Noise Exposure assessment leading to information bias		

Table S4. The template for assessment of quality and risk of bias of individual studies.

	Usual listening levels were measured while listening to initial 40 s of a pre-selected song ("Just like Heaven' by The Cure). During the test, subjects were blinded		
	from the iPod volume setting and told to set it to their usual listening level without considering preference to the test song. Individual LAeq8h was calculated for	Low	
	every single person based on estimation of the level of music and hours a day of listening to the music. Bias due to confounding		
	Subjects with exposure to other sources of loud noises (e.g., disco, concerts, school bands, noisy tools, home stereo) at least twice per month and prior ear problems	Low	
	were excluded from the study. No other confounders were taken into account (e.g., head trauma, drug ototoxicity, cigarette smoking). Bias due to selection of Participants		
	Subjects aged 13-16 years were recruited from three schools selected at random from the list of high schools located within 20 km of the authors' university. They		
	had to be regular users of PLDs for the previous six months. Participants were probably not randomly selected, and the response rate was not provided. Eight out of	Unclear	
	185 subjects were excluded due to ear abnormalities.		
	Health outcome assessment leading to information bias I Hearing thresholds were measured by means of pure-tone audiometry and extended high frequency audiometry. Subjects were requested to refrain from listening to their PLDs for 24 h prior to the hearing test. Tinnitus was self-reported,	Low	
	Health outcome assessment leading to information bias II		
	No information is provided about blinding the health outcome and/or exposure assessment.	Unclear	
	Total Risk of Bias in Study:		
	3/5 High		
	REFERENCE No 3		
Risk of Bias Check List for Studies on Noise and Health Outcomes	Study Name: Assessor Name: Evaluation of Early Hearing Damage in Personal Listening Device Users Using Extended High-Frequency Mariola Sliwinska-Kowalska Audiometry and Otoacoustic Emissions. Kamil Zaborowski Sulaiman et al., 2014 Sulaiman et al., 2014	Date Assessed: 10.12.2014	
Study Design	<u>Cross-sectional</u>		
Domain	Description of criteria for judgment		
	Noise Exposure assessment leading to information bias		
	Usual listening levels were measured while listening to initial 40 s of a pre-selected song ("Just like Heaven' by The Cure) in a quiet room (45-50 dBA ambient		
	noise level). During the test, subjects were blinded from the iPod volume setting and told to set it to their usual listening level without considering preference to the	Low	
	song. Individual LAeq8h was calculated for every single person based on estimation of the level of music and hours a day listen to the music. Bias due to confounding		

prior ear disorders and currently taken medications, including ototoxic drugs. Bias due to selection of Participants

Subjects aged 18-30 years were recruited voluntarily from the students and staff of one university, using strictly defined inclusion and exclusion criteria. Exposed

group of 35 subjects (users of PLDs for at least 1 year, 1 h/day and at >50% of the maximum volume setting) was sex- and age matched to the control group of 35

subjects who never or rarely used a PLD.

Health outcome assessment leading to information bias I

Hearing thresholds were measured by means of pure-tone audiometry and extended high frequency audiometry. TEOAE and DPOAE amplitude were measured

objectively. Subjects were requested to refrain from listening to their PLDs for 24 h prior to the hearing tests.

Health outcome assessment leading to information bias II

No information is provided about blinding the health outcome and/or exposure assessment.

Total Risk of Bias in Study:

3/5 High

REFERENCE No 4			
Risk of Bias Check List for	Study Name:	Assessor Name: Mariola Sliwinska-Kowalska	Date Assessed
Studies on Noise and Health	Exposure of High School Students to Noise from Personal Music Players in Quebec City, Canada.	Kamil Zaborowski	10.12.2014
Outcomes	Lévesque et al., 2010		
Study Design	<u>Cross-sectional</u>		
Domain	Description of criteria for judgment		Judgment of risk of bias
	Noise Exposure assessment leading to information bias		
	Individual LAeq.8h were calculated based on 2-min. measurement of music sounds listen through own PLD at "typical volume" and	d at "maximum level volume"; the	Low
	data about the daily average length of PLD use was taken from the questionnaire .		
	Bias due to confounding <i>No confounding factors included</i> Bias due to selection of Participants		High
	Students aged 14-17 years were recruited voluntarily from one high school. No inclusion or exclusion criteria specified. Lack of	randomization. Participation rate	High
	was 63.3%.		-
	Health outcome assessment leading to information bias I		

Low

Unclear

	No audiometric data. The presence of tinnitus was assessed by a questionnaire. Diagnostic criteria of tinnitus were not specified. It's not clear whether the outcome	High
	is a permanent tinnitus or transient tinnitus after listening to music.	
	Health outcome assessment leading to information bias II	
	No information is provided about blinding the health outcome and/or exposure assessment.	Unclear/High
	Total Risk of Bias in Study:	
	1/5 very high	
	REFERENCE No 5	
Risk of Bias Check List for Studies on Noise and Health	Study Name: Assessor Name: Mariola Sliwinska-Kowalska Risky Music Listening, Permanent Tinnitus and Depression, Anxiety, Thoughts about Suicide and Adverse General Kamil Zaborowski	Date Assessed: 10.12.2014
Outcomes	Health. Vogel et al., 2014	
Study Design	<u>Cross-sectional</u>	In dama and a f
Domain	Description of criteria for judgment	risk of bias
	Noise Exposure assessment leading to information bias	
	No direct measurement of noise levels. Average weekly exposure time to MP3 players was estimated by referring the volume of the device to dB(A) value and	Unclear/High?
	multiplying days per week and hours per day to calculate (weekly) Permissible Exposure Limits (PELweek = music level of 89 dBA listen for 56 h a week). Bias due to confounding	
	Values adjusted for age and gender	Low
	Bias due to selection of Participants A total of 1228 students, aged 16-25 years of 2 Dutch secondary vocational schools were invited. No randomization. Participation rate 77.9%	Low
	Health outcome assessment leading to information bias I	
	No audiometric data. The presence of "permanent hearing-related symptoms" were categorized as "I am constantly experiencing hearing symptoms (yes, no)".	
	There is not clear what proportion of subjects with "permanent hearing-related symptoms" experienced permanent tinnitus. Diagnostic criteria of permanent	High
	tinnitus were not specified. No validated method of tinnitus assessment.	
	Health outcome assessment leading to information bias II	
	No information is provided about blinding the health outcome and/or exposure assessment.	Unclear/High
	Total Risk of Bias in Study:	
	2/5 High	

Table S5.	The list	of included	and	excluded	studies.

Inclu	ded Studies
1.	Feder, K.; Marro, L.; Keith, S.E.; Michaud, D.S. Audiometric thresholds and portable digital audio player user listening habits. <i>Int. J. Audiol.</i> 2013, 52, 606-616. doi: 10.3109/14992027.2013.798687.
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