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Sleepiness of day shift workers and watchkeepers on board at high seas: a cross-sectional study

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Sleepiness of day shift workers and watchkeepers on board at high seas: a crosssectional study

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ABSTRACT

Objectives

To estimate the relevance of sleepiness on duty among day shift workers and watchkeepers on board.

Design

Cross-sectional survey in a maritime field study.

Setting

12 shipping companies with container vessels under German management.

Participants

The whole crew (75 day shift workers and 123 watchkeepers) during 18 voyages on container ships.

Outcome measures

Sleepiness on duty and efficiency of sleep by using pupillometry (in a cross-shift design) and SenseWear® armband activity monitor.

Results

The watchkeepers showed significantly shorter sleep periods than day shift workers (5.5 h vs. 5.8 h). The average efficiency of sleep was 69.6% and significantly lower among watchkeepers (OR 0.48; 95% CI 0.26-0.88). 396 pupillometric examinations were carried out and revealed 88 study members (22.2%) with a pupillary unrest index (rPUI) in a range characterized as "unfit for duty" and 110 seafarers (27.8%) categorized as "particular attention required". The average rPUI was similar between day shift workers and watchkeepers.

According to the Epworth Sleepiness Scale, the subjective judgement of 70 seafarers (35.4%) revealed recent daytime sleepiness, which was similarly often stated by day shift workers and watchkeepers. Based on the Stanford Sleepiness Scale (SSS), a measurable cross-shift increase in the SSS value during the examined shift could be objectified, especially among watchkeepers. The amount of time already spent on the vessel at the time of the present examination was significantly associated with the rPUI (p= 0.009).

Discussion

Sleep periods of both the day shift workers and the watchkeepers aboard vessels were alarmingly short and sleep efficiency was low. Sleepiness on duty is similarly prevalent

 among day shift workers and watchkeepers and seems to depend partly on the cumulative working period on the vessels.

Conclusion

Preventive measures need to be taken by the shipping industry.

Key words: occupational medicine, sleepiness, seafaring, pupillometry

Strengths and limitations of this study

- The present maritime field study provides for the first time the relevance of seafarers' sleepiness on duty during the sea passage, with the distinction of crew members with and without watchkeeping duties.
- The present study analysed seafarers' sleepiness on duty by applying both subjective and objective methods that are less dependent on the participants' motivation (pupillometry, armband activity monitor).
- The study was carried out in a cross-sectional design that does not allow evaluation of long-time effects of sleepiness.
- Due to the various occupational and ethnic groups on board, the crews are very heterogeneous; that makes the interpretation and comparison of sleeping behaviours difficult.

INTRODUCTION

Long and irregular working hours each day, combined with sleep deficiency and long periods of work at sea, are crucial risk factors for increased sleepiness on duty among seafarers.[1,2] Strong weather conditions can also affect seafarers' performance, increase the risk of error and, consequently, cause injuries or fatalities to personnel. Psychological strain in maritime professions can also lead to psychosomatic diseases including burnout syndrome or exhaustion (fatigue).[3] It has been stated that shipping crews suffer from psychophysical exhaustion/strain due to stress and decreased periods and quality of sleep.[4] Thus, seafaring still ought to be considered a high-risk profession for psychophysical exhaustion.[5,6]

Three voyage episodes can be distinguished on board: stays in port, river passages and sea passages. During the first two voyage episodes, the seafarers are often exposed to high psychophysical stressors caused by unforeseeable and external demands that possibly need to

 be addressed at chronobiologically adverse times (e.g. embarkation and disembarkation, loading and unloading, exchange of information with port authorities). During the sea passage, the engine room personnel, the electricians and the galley staff can often adhere to a regular working day of 8 hours (day shift workers). This is better suited to chronobiologically adapted sleep periods and can thus partially compensate for a potential sleep deficiency.[7] In contrast, due to obligatory navigation manoeuvres, nautical officers and a large number of the deck ratings are often required to work in a 24-hour shift system during sea passages (watchkeepers).

Nowadays, merchant ships operating internationally generally run on a 4/8-hour watch shift system. That means that three nautical officers alternate in a system, which includes four hours on duty and eight hours off for each of them. Van Leeuwen, Kircher et al. (2013)[8] measured the effect of a 4/8-hour watch shift system on the alertness of seafarers in a ship simulator. They observed that especially additional overtime was associated with a subjective and objective increase in sleepiness.

It has been described that watchkeeping, critical assignments during night time and irregular working periods can lead to disruptions of the crews' circadian rhythm as a precondition for sleepiness on board.[9] Dohrmann and Leppin (2017)[7] performed a systematic analysis and quality assessment of seafarers' fatigue. They observed that working nights was most fatiguing and that fatigue levels were higher toward the end of watch or shift. According to the review, particularly the psychosocial work environment (including day shift workers besides the watchkeepers) had received little attention. However, the monotonous noise of the vessel's engine, the smooth ship's vibrations and the continuous slow ship's movements (during calm weather conditions) can lead to sleepiness of the whole crew on board. Higher levels of exposition to noise and vibrations can also increase sleep troubles/problems and poorer sleep quality when impacting on employees throughout the day.[10]

Working in a maritime setting is characterized by a wide variety of occupations with numerous fatiguing physical and mental strains, depending on the type of job.[11] The available maritime fatigue studies have only focused on watch officers as crew members who typically also work during night hours.[2,8,12-14] Thus, there is a lack of knowledge about sleepiness at high seas among the other shipboard occupational groups, including the day shift workers. Knowing who is affected by severe sleepiness on board is of great importance to facilitate its prevention.

The present maritime field study analysed for the first time the relevance of seafarers' sleepiness on duty during the sea passage, with the distinction of day shift workers and watchkeepers on board.

METHODS

Study sample

A medically trained scientist accompanied 18 sea voyages on container ships operating in the Baltic Sea and examined the crew members on board. 206 out of 225 seafarers took part in the study (participation rate 91.6%). Only the results of those 198 seafarers were included who could be interviewed and examined (pupillometry) in a cross-shift design (both at the very beginning of their shift and at the end). Taking part in this study was voluntary and the individual data was pseudonymized. No patients were involved in this study. All participants gave their informed consent before taking part in this study. The study was approved by the Ethics Committee of the Hamburg Medical Association (no PV4395).

The 198 seafarers were classified into two occupational groups (75 day shift workers and 123 watchkeepers) (Tab. 1). Slightly more watchkeepers than day shift workers originated from Southeast Asian (109 from the Philippines and 4 from other Southeast Asian countries). The median age of the exclusively male study sample was 36.7 years (19 - 67 years) and significantly higher among the day shift workers. Furthermore, the day shift workers had a somewhat higher body weight than the watchkeepers. No differences were observed in the chronotype when comparing watchkeepers with day shift workers. The difference between the two occupational groups in terms of their marital status and the presence of children was not noteworthy. 49.0% of the seafarers either smoked or were former smokers.

	Day shift workers	Watchkeepers
	(54 engine room personnel,	(46 nautical officers, 77
	16 electricians, 5 galley staff)	deck ratings)
	75 (27.0%)	100 (60 10/)
Number; <i>n (%)</i>	75 (37.9%)	123 (62.1%)
Age ; years (min-max)	44 (19-67)	35 (19-63)
BMI; median (min-max)	26 (19-40)	24 (17-36)
Morning Evening Questic	onnaire, n (%)	
Morning type	45 (60.0%)	68 (55.2%)
Intermediate type	24 (32.0%)	46 (37.4%)
Evening type	6 (8.0%)	9 (7.4%)
Origin ; <i>n</i> (%)		
European	38 (50.7%)	47 (38.2%)
Southeast Asian	37 (49.3%)	76 (61.8%)
Married; n (%)	53 (70.7%)	87 (70.7%)
Children; n (%)	53 (70.7%)	82 (66.7%)
Smoking status; n (%)		
Never smoked	36 (48.0%)	65 (52.8%)
Former smoker/smoker	39 (52.0%)	58 (47.2%)

Tab. 1 Demographic and lifestyle parameters by occupational groups on board

To assess long-term effects on sleep during their current period on board, the participants were additionally grouped in respect of their stay on board at the time of examination (< 2 months, 2-5 months and > 5 months).

Examination procedure

All seafarers taking part in the study were examined with the SenseWear® armband monitor and pupillometry both during shifts and during time off (including sleep time). The present study monitored the sleep of all seafarers in a continuous mode during a period of at least 72 hours of observation. The average period of wearing the armband monitor was 66.3 h (SD 14.8 h) (>92% of observation time) and did not differ between the occupational groups. The pupillometric examination took place within this observation period.

Efficiency of sleep

The SenseWear® armband activity monitor is a device that weighs 82 g and is worn on the right upper arm just above the triceps muscle according to its validation requirements. The monitor is designed to analyse the profile of physical activity (movement, lying down or sleeping). The collected information allows the estimation of sleep efficiency by establishing the ratio of the duration of sleep and the time spent lying down. Thus, efficiency of sleep expresses the time spent actually sleeping while lying down.

The armband monitor has already been successfully applied in many studies as a detector of sleep.[15-19] Current studies reveal that the total sleep time and time in bed correlate significantly between the measurements of the armband monitor and the polysomnography (p<0.001); the armband has proved to be superior in comparison to other activity monitors.[16]

Pupillometry

The device *Fit-For-Duty* by AmTech was used to conduct pupillometric examinations. The Pupillographic Sleepiness Test is considered an objective method for documenting sleepiness by monitoring spontaneous and unconscious oscillations of the pupil without stimulating light. The result is a pupillogram, which can be used to deduct the pupillary unrest index (rPUI). This parameter therefore is an objective measure for the variance of the diameter of the pupil. A recent study suggested the Pupillographic Sleepiness Test as a reliable measurement for detecting drowsiness-related impairment.[20]

The rPUI is compared to standard values. Results < 1.02 are considered normal. "Particular attention required" is the characterization of results \geq 1.02 und < 1.53. An index \geq 1.53 is

rated as "unfit for duty". This methodology has repeatedly been used in scientific studies to assess sleepiness.[21-23]

During a sea passage, the pupillometric examination was performed twice according to a cross-shift design for all 198 seafarers included in the study sample. The chosen sea passages lasted for at least 24 hours and therefore allowed a regular operation of the vessel and predictable working procedures. The examination was performed within a timeframe of 30 minutes at the beginning and before the end of a regular working shift period.

The engine room personnel, the electricians and the galley staff (without watchkeeping duties) were examined during an average work shift that lasted 8 hours (most likely from 8:00 h to 17:00 h including a lunch break of 1 hour). The watchkeepers were randomly examined during one of the six shift periods (0-4 h, 4-8 h, 8-12 h, 12-16 h, 16-20 h und 20-24 h) with the aim of achieving an equal representation of the periods (about 20 watchkeepers/shift period).

Questionnaire

In the framework of a standardized interview, all seafarers were asked about their demographic data, their subjective physical and mental stress level, their sleep period before the examined shift and their current working time. Additionally, chronic fatigue was estimated by using the Epworth Sleepiness Scale.[24] The Stanford Sleepiness Scale assessed the sleepiness before and after a shift. In order to identify the daily peak of alertness, the seafarers filled in the Morningness-Eveningness Questionnaire (rMEQ).[25] The findings allowed the allocation of the participants to chronotypes.

Statistics

Statistic analysis was performed with SPSS (version 24, IBM Corporation). After investigation for normal distribution, the non-parametric tests (Mann Whitney-U test, Wilcoxon test) were used. The Chi-squared test was applied to analyse differences in frequencies of parameters. Crude odds ratio (OR) including 95% confidence intervals was calculated by binary logistic regression. For adjustment reasons, age, rank (officer vs. rating), the examination time of day and duration of stay on board at the time of examination were added. Furthermore, correlations were analysed by using the Spearman test. All indicated p-values were two-sided, and a p-value of < 0.05 was regarded as statistically significant.

RESULTS

The number of months day time workers had already spent on the vessel at the time of examination and during their current contract was similar to that of watchkeepers. In particular, the stratification of the seafarers in tertile concerning their recent stay on board did not reveal any differences (Tab. 2).

The Epworth Sleepiness Scale (ESS) showed that 70 seafarers (35.4%) had recently been suffering from daytime sleepiness. Depending on a growing stay on board, the ESS value increased significantly (p= 0.004). No differences were observed when differentiating according to the obligation to perform watchkeeping duties (p= 0.113). Younger seafarers below the age median of 37 years indicated daytime sleepiness more often than older colleagues (p= 0.014).

	Occupational groups		
	Day shift workers	Watchkeepers	р
	(n=75)	(n=123)	
Stay on board			
At the time of examination; months (min-max)	3 (1-12)	3 (0-11)	0.837
Frequency according to tertile; n (%)			
≤ 2 months	28 (37.3%)	45 (36.6%)	
> 2 and \leq 5 months	28 (37.3%)	45 (36.3%)	0.973
> 5 months	19 (25.3%)	33 (26.8%)	
Scheduled (min-max)	7 (2-13)	8 (1-12)	0.719
Epworth Sleepiness Scale (ESS))		
Score value (SD) ¹	8 (0-15)	8 (0-21)	0.113
	26 (34.7%)	44 (35.8%)	0.875

Tab. 2 Stay on board and subjective assessment for daytime sleepiness

Cross-shift examinations

To analyse the recent alertness attributed to a representative shift, 198 seafarers were asked to participate in a cross-shift examination. According to the results of the armband monitor, the sleep time before the examined shift lasted for 5.6 hours (SD 1.0) per 24 h period, while watchkeepers had significantly shorter sleep durations compared to the day shift workers (Tab. 3). The working hours during the current shift did not differ between these groups. Concerning their subjective stress level during the shift examined, significantly more watchkeepers experienced mental demands than day shift workers (OR 2.35; 95% CI 1.24-4.44). After adjustment for age, ranking, examination time of day and recent number of months at the time of investigation, this elevated risk for mental stress remained significant among watchkeepers.

During the examined shift, the average sleep efficiency was 69.3% and was significantly lower among watchkeeping seafarers than day shift workers (OR 0.48; 95% CI 0.26-0.88). This finding was independent of the age, ranking, time of day of the examination and the recent duration of shipboard stay.

Before their shift, the mean value on the Stanford Sleepiness Scale (SSS) was 2.6 (SD 1.4) (2= "functioning at high levels, but not fully alert"; 3= "awake, but relaxed; responsive but not fully alert"); after the work shift, the level of sleepiness was significantly higher (3.2 (SD 1.8)) (Wilcoxon test: p= 0.001) indicating a measurable increase in the subjective sleepiness in the course of a shift. This was especially true for watchkeepers (Tab. 3). Consequently, more watchkeepers reported current sleepiness than day shift workers after the examined shift.

A remarkable number of 35 seafarers (17.7%) reported a level of sleepiness on duty of 6/7 on the SSS (6= "sleepy, woozy, fighting sleep, prefer to lie down"; 7= "no longer fighting sleep; sleep onset soon; having dream-like thoughts") at the end of their shift. According to SSS, it turned out that more young seafarers considered themselves to be tired (cross-shift SSS of all crew members below and above the median age of 37 years: 3.1 vs. 2.6; p= 0.011). Focusing on the group of watchkeeping seafarers, those who were on duty between 00:00-04:00 h and 04:00-08:00 h more often displayed severe sleepiness on duty at the end of their shift (SSS \geq 5) (50.0% and 72.2% respectively).

The 396 pupillometric examinations (during the first and the last 30 minutes of a shift) revealed that the change in rPUI values during the cross-shift observation did not reach a significant level in intra-individual comparison (mean rPUI before vs. after the working shift: 1.14 vs. 1.19;

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cross-shift rPUI change: p= 0.355). After stratification, the intra-individual cross-shift change in rPUI values was also not dependent on the occupational groups (Tab. 3).

The objective sleepiness on duty in the study sample was not dependent on age (only a slight tendency for younger seafarers after shift; p= 0.064). During the examination, 12 seafarers fell asleep and therefore were assigned to the group "unfit for duty". The pupillary unrest index in 88 examinations showed the seafarers were "unfit for duty"; additionally "particular attention required" was classified in 110 cases (27.8%). Therefore, only half of the examinations were "normal". No differences were observed in the pupillary unrest index between seafarers with and without watchkeeping duties.

In concordance to their subjective self-report in SSS, watchkeepers displayed somewhat higher rPUI values after the shift than day shift workers (Tab. 3). The analysis of the correlation of the subjective assessment of sleepiness on duty (SSS) with the objective measures of pupillometry only revealed a very weak correlation after the shift (r= 0.185; p= 0.009).

Within the group of watchkeepers, stronger sleepiness on duty (rPUI \ge 1.2) after a shift lasting from 00:00-04:00 h and from 04:00-08:00 h could be objectified (75.0% and 55.6% respectively).

	Day shift workers (n=75)	Watchkeepers (n=123)	Crude OR * (95% Cl)	Adjusted OR [#] (95% Cl)
Time periods in the con	text of the current p	upillometric exami	nation, hours (SD)	
Sleep period before ¹	5.8 (1.1)	5.5 (1.0)	2.05 (1.10-3.83)	2.32 (1.21-4.47)
Working hours	9.5 (1.5)	9.6 (1.8)	1.02 (0.55-1.88)	0.74 (0.38-1.44)
Subjective stress level of	during examined shi	i ft, n (SD)		
Physical ²	48 (64.0%)	78 (63.4%)	0.96 (0.52-1.79)	0.51 (0.24-1.08)
Mental ³	41 (54.7%)	94 (76.4%)	2.35 (1.24-4.44)	2.18 (1.08-4.40)
Sleep efficiency ¹				
- Mean (%)	72.7% (11.8%)	67.9% (12.2%)	0.48 (0.26-0.88)	0.48 (0.25-0.91)
		11		

Stanford Sleepiness Scale	e (SSS)⁴				
Cross-shift , - Mean (SD)⁵	2.6 (1.4)	3.1 (1.7)	0.73 (0.48-1.10)	0.84 (0.55-1.29)	
Time depending					
- At the beginning of the shift	2.5 (1.4)	2.6 (1.5)	1.07 (0.59-1.95)	0.91 (0.49-7.70)	
- After the shift	2.8 (1.4)	3.5 (1.9)	1.81 (1.01-3.25)	1.25 (0.66-2.37)	
Pupillary unrest index (rPl	UI)				
Cross-shift , - Mean⁵ (SD)	1.14 (0.66)	1.18 (0.65)	0.92 (0.61-1.40)	1.05 (0.70-1.61)	
Time depending					
 At the beginning of the shift 	1.14 (0.67)	1.12 (0.62)	0.96 (0.52-1.74)	0.86 (0.46-1.61)	
- After the shift	1.13 (0.66)	1.23 (0.65)	1.55 (0.85-2.84)	1.31 (0.70-2.46)	
Level (n=396) of sleepines	s on duty⁵n (%)				
- None ⁶	78 (52.0%)	120 (48.8%)			
- Particular attention	39 (26.0%)	71 (28.9%)	0.789		
required ⁷					
- Unfit for duty ⁸	33 (22.0%)	55 (22.3%)			
*the crude OR bases or groups and the examina stay on board at the tim	ation time of day #			·	
¹ according to measurements with the armband monitor, related to an average 24 hour period ² "have you experienced physical stress during the examined shift?" ³ "have you experienced mental stress during the examined shift?"					
⁴ SSS-scale from 1 ("fee	⁴ SSS-scale from 1 ("feel active and vital") up to 7 ("almost dreaming/falling asleep")				
⁵ all values exploited (be			• • •		
Tab. 3 Cross-shift exan	nination concerning	sleep characterist	tics		

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Regardless of the occupational groups, the objective sleepiness on duty (rPUI) did not correlate to the sleep period before the examined shift, the sleep efficiency, the current working hours and the objective assessment of the ship's motion according to the ship's journal parameters. An association was observed, however, between the duration of time already spent on board at the time of the seafarers' examination and the rPUI (p= 0.009). The stratification according to the duration of stay on board indicates that the association was especially true for those seafarers with a longer stay on the vessels (pre-shift rPUI after stay of less than 2 months, 2-5 months and more than 5 months: 1.06, 1.09 and - much higher - 1.32). The bivariate grouping of the crew in their stay of less vs. more than 5 months showed significant pre-shift differences in rPUI (1.08 vs. 1.32; p= 0.002).

DISCUSSION

Being a seafarer requires strong mental stability and a robust physical constitution, along with an adaptive and flexible attitude. However, stress and fatigue can hinder maritime professionals in performing effectively.[26] Seafarers spend both their working and leisure time over a couple of months in the restricted shipboard environment that can impact sleep quality and lead to sleepiness.[5] In the present study, a significantly lower sleep efficiency averaging at 69.3% and a higher subjective sleepiness assessment (SSS) after the shift were found among watchkeepers compared to day shift workers. In addition, the examinations carried out on board objectified critically short durations of the seafarers' sleep average (5.6 h per 24 h) particularly among watchkeepers.

Especially the short sleeping times correspond very well with the results of international studies.[27] Sleep periods on board are often interrupted (potentially due to ship's movements or sudden noise evoked by the handling of containers in harbours).[28] These interruptions are often an inevitable consequence of the watch shift requirements with two 4-h working shifts per day. Thus, on any watch system it is common that seafarers have several sleep episodes per 24-h period. Daytime sleep is usually much less efficient than sleep obtained at the circadian nadir.

Although this study has not proven that sleepiness on duty depends directly on disturbances of the sea during passages, we measured low sleep efficiency. This means that not only the amount, but also the quality of sleep is insufficient among the examined seafarers on board. Frequent sleep disruptions can impair alertness to a great degree and consequently lead to an increased risk of accident on board.[29]

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In contrast to a similar physical stress level and working hours per day, the crew members with watchkeeping duties experienced mental stress subjectively more frequently than day shift workers. This was probably due to their reduced and interrupted sleep time as well as their high job responsibility, which represents a distinct mental stressor. Correspondingly, the watchkeepers starting with a similar subjective sleepiness level compared with the day shift workers had a significantly more pronounced increase of their sleepiness after the cross-shift examination. Although no significance level war reached, the cross-shift pupillometry of watchkeepers also indicated a higher level of objective sleepiness after the shift than that of day shift workers.

According to Wilhelm (2008)[30], severe sleepiness is displayed by drivers who did not sleep during the chronobiologically relevant time frame (0:00 h - 05:00 h). In the maritime setting, this especially applies to watchkeepers. These crew members, who are on duty during the inconvenient time frames between 0:00-04:00 h and 04:00-08:00 h, reported the expected subjective severe sleepiness, which could also be objectified by pupillometric measurements. In this context, it has to be taken into account that most fatigue-induced shipping disasters take place in these time frames.[8]

Watchkeepers are habitual shift workers, often experiencing circadian misalignment due to their irregular work/rest schedules. This might be one explanation as to why the small number of available maritime field studies about seafarers' fatigue has exclusively focused on watchkeepers. Importantly, this study demonstrates that day shift workers also often experience severe sleepiness; more than 20% of both the watchkeepers and the day shift workers were characterized as "unfit for duty" during their regular shift and only every second pupillary measurement was regarded normal. The fact that 12 seafarers had fallen asleep during the 11-min pupillary examination and that 35 crew members regarded themselves as very sleepy post-shift (SSS \geq 6) confirms these alarming pupillometric results. In light of the strong impact on the ships' safety, further studies are urgently needed to examine and counteract the sleepiness of both the shipboard watchkeepers and the day shift workers.

The period already spent on the vessel at the time of the examination seems to influence sleepiness on duty. Officers, generally coming from European countries, normally have far shorter periods on board than ratings (averaging 2.5 vs. 4.1 months in a row). It is most likely that the differences detected in sleepiness on duty related to recent shipboard stay are mainly being caused by the cumulative working time on board. Daily sleepiness as a consequence of high work strain lasting for many months seems to be plausible. According to the present results, working periods below five months in a row seem to be reasonable for

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seafarers. Further studies are required to determine recommendations for maximum working periods on board.

Subjective assessments of sleepiness only displayed a weak correlation with the results of the pupillometry that could be objectified. This could lead to a misjudgement of their current psychophysical performance, which might also have safety implications. Younger and less experienced crew members reported more severe sleepiness on duty but did not display differences in their pupillometric measurements. In view of the frequently described high prevalence of fatigue-related accidents in seafaring, a high level of psychophysical stress, but also a misjudgement of their alertness is assumed. Thus, it is recommended to use complementary objective methods besides questionnaires in studies to determine the level of fatigue among examined employees.

Recent studies have described a difference in the circadian rhythm among various ethnic groups, for example more Africans were allocated to "morning type" compared to a fair-skinned reference group.[31,32] In the present study, the Morningness-Eveningness Questionnaire also revealed significant chronotypical differences between the members of this study sample when they were grouped according to their origin (data not shown); Southeast Asians were more frequently assigned to the morning type than Europeans (65.4% vs. 32.2%; p< 0.001). Therefore, it is possibly easier for Southeast Asians than for Europeans to perform work duties at times considered to be chronobiologically inconvenient (e.g., from 04:00 h to 08:00 h). Future studies should explore possibilities and evaluate acceptance by the crew to develop more flexible shift scheduling that allows the consideration of chronotype and, possibly, individual preferences of the watchkeeping seafarers.

Limitations

The present analysis has some limitations that need to be addressed. Firstly, the sample size of this study is rather small, but in comparison to other available maritime studies the examined seafarer population is far larger. Secondly, the study was carried out in a cross-sectional design that does not allow the evaluation of long-time effects of sleepiness. Due to the permanently changing shipping crews on the vessels, it is hardly possible to arrange long-time follow-up examinations of a noteworthy proportion of seafarers. Thirdly, due to the various occupational and ethnic groups on board, the crews are very heterogeneous and that makes the interpretation and comparison of sleeping behaviours difficult, also when considering the large inter-individual and intra-individual variability in sleep. Fourthly, the present study design does

not provide information about the seafarers' sleep architecture. Sleep loss is generally compensated by changing the sleep architecture towards more so-called slow-wave sleep. Despite these limitations, the present study analyses for the first time the relevance of sleepiness in seafarers with and without watchkeeping duties that require further confirmation in a larger cohort. Furthermore, the present maritime field study analysed the relevance of seafarers' sleepiness on duty by applying various subjective and objective methods. Up to now, most maritime studies about seafarers' sleepiness have not been carried out on board of vessels and only rely on subjective methods.[33] Questionnaires are, however, subjective instruments, consequently depending on self-reported data, so that underreporting might have occurred.[34] Additionally, these subjective instruments do not reveal biophysiological differences that might promote the understanding of sleepiness on board.[20,35]

Nowadays, a variety of subjective and objective instruments exist for assessment of excessive daytime sleepiness, including structured sleep history, sleep logs and sleep questionnaires. The multiple sleep latency test, for example, is often used as an objective measurement to evaluate sleep propensity. However, in view of the large overlap between healthy subjects and subjects with sleep disorders, its use to assess sleepiness is questionable.[36] Furthermore, its results are often jeopardized by motivational influences and the last nap effect.[35] Consequently, a feasible and convenient method that is less dependent on motivation - such as the pupillometry used in this study - seems to constitute an enrichment in field studies.[20,36]

Implications for clinicians and policy makers

Fatigue in the maritime setting could be counteracted by strict compliance with and monitoring of the obligatory rest and sleep times. According to Allen, Wadsworth et al. (2007)[34] it is not uncommon in seafaring for legal obligations to be neglected, for example by ignoring the minimum safety levels for crewing on board. To reduce the seafarers' workload on board during the vessel's stay in the port, some job duties could be transferred to land-based workers ashore.

In light of the frequently objectified sleepiness on duty within the study sample, training should be offered for shipboard crews to improve sleep hygiene and techniques to support short-term recreation, such as power napping. This training should be accompanied by the strengthening of the seafarers' individual resources (e.g. training to cope with stress for health promotion[37]) to enable them to compensate for the inevitable psychophysical strain on board. Considering the present results, limiting the work periods of seafarers (perhaps to a maximum of five months) might be an essential preventive measure in a maritime setting.

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Contributors

MO and HJJ gave substantial contributions to the conception or design of the work or the acquisition, analysis or interpretation of data. They were equally involved in drafting the work or revising it critically for important intellectual content. Both authors gave their final approval of the version published.

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Conflict of interest

Both authors declare no conflicts of interest.

Patient consent

Not required.

Ethics approval

The study was approved by the Ethics Committee of the Hamburg Medical Association (no. PV4395).

Data sharing statement

No additional data are available.

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STROBE Statement—Checklist of items that should be included in reports of	cross-sectional studies
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	Item No	Recommendation	Pag No
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used term in the title or the abstract	1
		(<i>b</i>) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			I
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5,7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	5,6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7,8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7,8
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	
		(<i>d</i>) If applicable, describe analytical methods taking account of sampling strategy	
		(<i><u>e</u></i>) Describe any sensitivity analyses	
Results			
Participants	13*	 (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed 	9
		(b) Give reasons for non-participation at each stage	
	4 4-1-	(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted	10-
		estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12

		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute	11
		risk for a meaningful time period	
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and	
		sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias	15-
		or imprecision. Discuss both direction and magnitude of any potential bias	16
Interpretation	20	Give a cautious overall interpretation of results considering objectives,	15-
		limitations, multiplicity of analyses, results from similar studies, and other	16
		relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study	17
		and, if applicable, for the original study on which the present article is based	

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org. BMJ Open

BMJ Open

Sleepiness of day workers and watchkeepers on board at high seas: a cross-sectional study

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3 4	1	Sleepiness of day workers and watchkeepers on board at high seas: a cross-sectional
5	2	study
6 7	_	
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17 ABSTRACT

18 Objectives

To estimate the prevalence of sleepiness on duty among day workers and watchkeepers onboard.

21 Design

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22 Cross-sectional survey in a maritime field study.

23 Setting

24 10 shipping companies with container vessels under German management.

25 Participants

The whole crew (75 day workers and 123 watchkeepers) during 18 voyages on 18 different container ships.

28 Outcome measures

⁷ 29 Sleepiness on duty and efficiency of sleep using pupillometry (in a cross-shift design) and the
 ⁸ 30 SenseWear® armband activity monitor.

31 Results

The watchkeepers showed significantly shorter sleep periods than day workers (5.5 h vs. 5.8 h). The average efficiency of sleep was 69.6% and significantly lower among watchkeepers (OR 0.48; 95% CI 0.26-0.88). 396 pupillometric examinations were carried out and revealed 88 study members (22.2%) with a pupillary unrest index (rPUI) in a range characterised as "unfit for duty" and 110 seafarers (27.8%) categorised as "particular attention required". The average rPUI was similar between day workers and watchkeepers. The Epworth Sleepiness Scale revealed recent daytime sleepiness in 70 seafarers, which

- 39 was similarly often stated by day workers and watchkeepers. Based on the Stanford
- 40 Sleepiness Scale (SSS), a measurable cross-shift increase in the SSS value during the
- $\frac{1}{8}$ 41 examined shift was observed, especially among watchkeepers. The amount of time already
- ¹⁹ 42 spent on the vessel at the time of the present examination was significantly associated with
 - 43 the rPUI (p= 0.009).

44 Conclusion

45 Sleep periods of both the day workers and the watchkeepers aboard vessels were alarmingly

- 46 short and sleep efficiency was low. Sleepiness on duty is similarly prevalent among day
- ³ 47 workers and watchkeepers and seems to depend partly on the cumulative working period on
 - 2

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3	48	the vessels. Preventive measures need to be taken by the shipping industry to counteract
4 5	49	fatigue (e.g. through compliance with the obligatory rest and sleep times).
6 7	50	
8 9	51	Key words: occupational medicine, sleepiness, seafaring, pupillometry
10 11	52	
12 13 14	53	Strengths and limitations of this study
15	54	The present maritime field study provides for the first time the prevalence of seafarers'
16 17	55	sleepiness on duty during the sea passage, drawing a distinction between crew members
18	56	with and without watchkeeping duties.
19 20	57	> The present study analysed seafarers' sleepiness on duty by applying both subjective and
21 22	58	objective methods that are less dependent on the participants' motivation (pupillometry,
23	59	armband activity monitor).
24 25	60	The study was carried out in a cross-sectional design that does not allow evaluation of
26	61	long-time effects of sleepiness.
27 28	62	Due to the various occupational and ethnic groups on board, the crews are very
29	63	heterogeneous; that makes the interpretation and comparison of sleeping behaviours
30 31	64	difficult.
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35 36	66	INTRODUCTION
37	67	Long and irregular working hours each day, combined with sleep deficiency and long periods
38 39	68	of work at sea, are crucial risk factors for increased sleepiness on duty among seafarers.[1,2]
40 41	69	Strong weather conditions can also affect seafarers' performance, increase the risk of error
42	70	and, consequently, cause injuries or fatalities to personnel. Psychological strain in maritime
43 44	71	professions can also lead to psychosomatic diseases including burnout syndrome or
45	72	exhaustion.[3] Some studies have stated that shipping crews suffer from psychophysical
46 47	73	exhaustion/strain due to stress and decreased periods and quality of sleep.[4] Thus, seafaring
48 49	74	still ought to be considered a high-risk profession for psychophysical exhaustion.[5,6]
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51 52	75	Three voyage episodes can be distinguished on board: stays in port, river passages and sea
53 54	76	passages. During the first two voyage episodes, the seafarers are often exposed to high
55	77	psychophysical stressors caused by unforeseeable and external demands that possibly need to
56 57	78	be addressed at chronobiologically adverse times (e.g. embarkation and disembarkation,
58	79	loading and unloading, exchange of information with port authorities). During the sea passage,
59 60	80	the engine room personnel, the electricians and the galley staff can often adhere to a regular 3

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working day of 8 hours (day workers). This is better suited to chronobiologically adapted sleep
periods and can thus partially compensate for a potential sleep deficiency.[7] In contrast, due to
obligatory navigation manoeuvres, nautical officers and a large number of the deck ratings are
often required to work in a 24-hour shift system during sea passages (watchkeepers).

Nowadays, merchant ships operating internationally generally run on a 4/8-hour watch shift system. That means that three nautical officers alternate in a system which includes four hours on duty and eight hours off for each of them. Van Leeuwen, Kircher et al. (2013)[8] measured the effect of a 4/8-hour watch shift system on the alertness of seafarers in a ship simulator. They observed that especially additional overtime was associated with a subjective and objective increase in sleepiness. The authors also showed sleepiness increasing with time on watch and peaking at the end of a watch.

It has been described that watchkeeping, critical assignments during night time and irregular working periods can lead to disruptions of the crews' circadian rhythm as a precondition for sleepiness on board.[9] Dohrmann and Leppin (2017)[7] performed a systematic analysis and quality assessment of seafarers' fatigue. They observed that working nights was most fatiguing and that fatigue levels were higher toward the end of a watch or shift. According to the review, particularly the psychosocial work environment (including day workers besides the watchkeepers) had received little attention. However, the monotonous noise of the vessel's engine, the smooth ship's vibrations and the continuous slow ship's movements (during calm weather conditions) can lead to sleepiness of the whole crew on board. Higher levels of exposure to noise and vibrations can also increase sleep troubles/problems and poorer sleep quality when impacting on employees throughout the day.[10]

Working in a maritime setting is characterised by a wide variety of occupations with numerous fatiguing physical and mental strains, depending on the type of job.[11] The available maritime fatigue studies have only focused on watch officers as crew members who typically also work during night hours. [2,8,12,13] Thus, there is a lack of knowledge about sleepiness on the high seas among the other shipboard occupational groups, including the day workers. Knowing who is affected by severe sleepiness on board is of great importance to facilitate its prevention.

The present maritime field study analysed for the first time the prevalence of seafarers'
 sleepiness on duty during the sea passage, with a distinction between day workers and
 watchkeepers on board.

- ⁵⁶ 112

113 METHODS

114 Study sample

A medically trained scientist accompanied 18 sea voyages on 18 different container ships operating in the Baltic Sea and examined the crew members on board. 206 out of 225 seafarers took part in the study (participation rate 91.6%). Only the results of those 198 seafarers were included who could be interviewed and examined (pupillometry) in a cross-shift design (both before the beginning and after the end of their shift). Taking part in this study was voluntary and the individual data was pseudonymised. No patients were involved in this study. All participants gave their written informed consent before taking part in this study. The study was approved by the Ethics Committee of the Hamburg Medical Association (no PV4395).

The 198 seafarers were classified into two occupational groups (75 day workers and 123 watchkeepers) (Tab. 1). The median age of the exclusively male study sample was 36.7 years (19 - 67 years) and significantly higher among the day workers. Furthermore, the day workers had a somewhat higher body weight than the watchkeepers. No differences were observed in the circadian preference when comparing watchkeepers with day workers. The difference between the two occupational groups in terms of their marital status and the presence of children was not noteworthy. 49.0% of the seafarers either smoked or were former smokers.

37 132

³⁸ ³⁹ 133 Patient and Public Involvement

The present study focused on the sleepiness of shipboard crews; patients and/or public were not the target group of this study. Previous studies revealed that sleepiness constitutes one of the major problems amongst seafarers. All German shipping companies owning container ships were invited to participate in this study. 10 shipping companies agreed and put 18 different container ships at our disposal.

All seafarers on board of these vessels were informed about our study design, aim and
 140 content and were encouraged to participate. After completion of our board examination, an
 individual medical report was created and sent to each of the accepting seafarers to their
 home address.

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2 3			Davisser	Wetchkeen en
4			Day workers	Watchkeepers
5			(54 engine room personnel,	(46 nautical officers, 77
6 7			16 electricians, 5 galley staff)	deck ratings)
8 9 10		Number; <i>n (%)</i>	75 (37.9%)	123 (62.1%)
11 12 13		Age; median years (min-	44 (19-67)	35 (19-63)
14 15 16		max) BMI; median (min-max)	26 (19-40)	24 (17-36)
17 18 19		Morning Evening Question	nnaire, n (%)	
20 21 22		Morning type	45 (60.0%)	68 (55.2%)
23 24 25		Intermediate type	24 (32.0%)	46 (37.4%)
26 27 28		Evening type	6 (8.0%)	9 (7.4%)
29 30		Origin ; <i>n</i> (%)		
31 32 33		European	38 (50.7%)	47 (38.2%)
34 35		Southeast Asian Married; n (%)	37 (49.3%) 53 (70.7%)	76 (61.8%) 87 (70.7%)
36 37 38		Children; n (%)	53 (70.7%)	82 (66.7%)
39 40 41		Smoking status; n (%)		
42 43 44		Never smoked	36 (48.0%)	65 (52.8%)
45 46		Former smoker/smoker	39 (52.0%)	58 (47.2%)
47 48 49	144	Tab. 1 Demographic and life	estyle parameters by occupationa	l groups on board
50 51 52	145			
53	146	To assess long-term effects	on sleep during their current peri	od on board, the participants
54 55	147	were additionally grouped in	respect of their stay on board at	the time of examination (< 2
55 56 57	148	months, 2-5 months and > 5	i months).	
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50 **Examination procedure**

All seafarers taking part in the study were examined with the SenseWear® armband monitor and pupillometry both during shifts and during time off (including sleep time). These devices were selected because they did not considerably disturb the crew's daily routines (low weight, no cable connection, easy use), which was a precondition. The present study monitored the sleep of all seafarers in a continuous mode during a period of at least 72 hours of observation. An observation time of at least 3 days during the sea passage was chosen because of the known variations of sleep quality on a daily basis.

The average period of wearing the armband monitor was 66.3 h (SD 14.8 h) (>92% of
observation time) and did not differ between the occupational groups. The pupillometric
examination took place within this observation period.

162 Efficiency of sleep

The SenseWear® armband activity monitor is a device that weighs 82 g and is worn on the right upper arm just above the triceps muscle according to its validation requirements. While wearing the armband monitor, the seafarers could easily operate the device for themselves without support from the shipboard examiner. The monitor is designed to analyse the profile of physical activity (movement, lying down or sleeping). The collected information allows the estimation of sleep efficiency by establishing the ratio of the duration of sleep and the time spent lying down. Thus, efficiency of sleep expresses the time spent actually sleeping while lying down.

171 The armband monitor has already been successfully applied in many studies as a detector of
 172 sleep.[14-19] Current studies reveal that the total sleep time and time in bed correlate
 173 significantly between the measurements of the armband monitor and the polysomnography
 174 (p<0.001); the armband has proved to be superior in comparison to other commercially
 175 available activity monitors.[16]

177 **Pupillometry**

178 The device *Fit-For-Duty* by AmTech was used to conduct pupillometric examinations [20].

- ¹⁶ 179 The Pupillographic Sleepiness Test is considered an objective method for documenting
 - 180 sleepiness by monitoring spontaneous and unconscious oscillations of the pupil without

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stimulating light. The result is a pupillogram, which can be used to deduct the pupillary unrest index (rPUI). This parameter therefore is an objective measure for the variance of the diameter of the pupil. A recent study suggested the Pupillographic Sleepiness Test as a reliable measurement for detecting drowsiness-related impairment.[21]

The rPUI is compared to standard values. Results < 1.02 are considered normal. "Particular attention required" is the characterisation of results \geq 1.02 and < 1.53. An index \geq 1.53 is rated as "unfit for duty". This methodology has repeatedly been used in scientific studies to assess sleepiness.[22-24]

During a sea passage, the pupillometric examination was performed twice according to a cross-shift design for all 198 seafarers included in the study sample. The chosen sea passages lasted for at least 24 hours and therefore allowed a regular operation of the vessel and predictable working procedures. The pupillometric cross-shift examination took place 15 minutes before the respective shift started and directly after it ended so that that shift was neither shortened nor disturbed by this examination. In general, it is not likely that the seafarers were distinctly disturbed by the examination with the chosen devices or by the presence of the medical staff on board.

The engine room personnel, the electricians and the galley staff (without watchkeeping duties) were examined during an average work shift that lasted 8 hours (most likely from 8:00 h to 17:00 h including a lunch break of 1 hour). As watchkeepers have two work units per day -each of them about 4 h (six shift periods: 0-4 h, 4-8 h, 8-12 h, 12-16 h, 16-20 h and 20-24 h) - a split sleeping time is often observed in this occupational group. The watchkeepers were examined during a randomly selected shift period with the aim of achieving an equal representation of these periods (about 20 watchkeepers/shift period). For the assessment of cross-shift reactions, it was unavoidable to compare the PUI and SSS between two occupational groups with different lengths of working times.

Questionnaire

In the framework of a standardised interview, all seafarers were asked about their demographic data, their subjective physical and mental stress level, their sleep period before the examined shift and their current working time. Additionally, daytime sleepiness was estimated by using the Epworth Sleepiness Scale. [25] The Stanford Sleepiness Scale assessed the sleepiness before and after a shift. For the assessment of the circadian preference, the seafarers filled in the Morningness-Eveningness Questionnaire (rMEQ).[26]

1		
2 3 4	214	Statistics
5 6	215	Statistic analysis was performed with SPSS (version 24, IBM Corporation). The Shapiro-Wilk
7	216	test was used to test for normal distribution of data. Where variables were not normally
8 9	217	distributed, non-parametric tests (Mann Whitney-U test, Wilcoxon test) were used. The Chi-
10 11	218	squared test was applied to analyse differences in frequencies of parameters. Crude odds
12	219	ratio (OR) including 95% confidence intervals was calculated by binary logistic regression.
13 14	220	For adjustment reasons, age, rank (officer vs. rating), the examination time of day and
15	221	duration of stay on board at the time of examination were added. Furthermore, correlations
16 17	222	were analysed by using the Spearman test.
18 19	223	All indicated p-values were two-sided, and a p-value of < 0.05 was regarded as statistically
20	225	significant.
21 22	224	significant.
23	225	
24 25	226	
26 27	220	
28	227	RESULTS
29 30	228	The number of months day workers had already spent on the vessel at the time of examination
31 32	229	and during their current contract was similar to that of watchkeepers. In particular, the
33	230	stratification of the seafarers in tertiles concerning their recent stay on board did not reveal any
34 35	231	differences (Tab. 2).
36	201	
37 38	232	The Epworth Sleepiness Scale (ESS) showed that 70 seafarers (35.4%) had recently been
39 40	233	suffering from daytime sleepiness. The ESS value increased significantly (p= 0.004) with the
41	234	length of stay on board. No differences were observed when differentiating according to the
42 43	235	obligation to perform watchkeeping duties (p= 0.113). Younger seafarers below the age
44	236	median of 37 years indicated daytime sleepiness more often than older colleagues (p= 0.014).
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1 2				
3 4		Occupational groups		
5		Day workers	Watchkeepers	p
6 7		(n=75)	(n=123)	٢
8 9	Stay on board			
10 11	-			
12	At the time of examination;	3 (1-12)	3 (0-11)	0.837*
13 14	median months (min-max)			
15 16	Frequency according to			
17	tertile; n (%)			
18 19	≤ 2 months	28 (37.3%)	45 (36.6%)	
20 21	> 2 and ≤ 5 months	28 (37.3%)	45 (36.3%)	0.973#
22 23	> 5 months			
24		19 (25.3%)	33 (26.8%)	
25 26	Scheduled (min-max)	7 (2-13)	8 (1-12)	0.719*
27 28	Epworth Sleepiness Scale (ESS)	, median (min-max)		
29	Score value (SD) ¹	8 (0-15)	8 (0-21)	0.113*
30 31	≥ Cut off value (10), n (%)	26 (34.7%)	44 (35.8%)	0.875#
32 33 2 38			х <i>у</i>	
³⁴ 35 239	up to 24 ("maximum chance to doz	e in")	·	·
36 240	Tab. 2 Stay on board and subjectiv	e assessment for davtime	sleepiness	
37 ²⁴⁰ 38			cicopinece	
39 241 40				
⁴¹ 242	Cross-shift examinations			
42 - 12 13				
14 243		-		
16 Z44		· ·		
17 245	•	, , , , , , , , , , , , , , , , , , ,		ed tor
246 9 246		•	• • •	
1	1 5		•	
2 248 3 240	shift were significantly lower amongst watchkeepers. Concerning their subjective stress level			
3 249 4		during the shift examined, significantly more watchkeepers experienced mental demands		
5 250	than day workers (OR 2.35; 95% CI 1.24-4.44). After adjustment for age, ranking,			
6 7 251	examination time of day and recent	t number of months at the	time of investigation, this	
58 252 59	elevated risk for mental stress remained significant among watchkeepers.			
59 50		10		

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as significantly
10 26 0 99) This
l 0.26-0.88). This
on and the recent
t they had
ion on board
) was 2.6 (SD 1.4)
responsive but not
gher (3.2 (SD 1.8))
ve sleepiness in the
ength of their
uently, more
mined shift.

A remarkable number of 35 seafarers (17.7%) reported a level of sleepiness on duty of 6/7 on the SSS (6= "sleepy, woozy, fighting sleep, prefer to lie down"; 7= "no longer fighting sleep; sleep onset soon; having dream-like thoughts") after their shift. According to SSS, more young seafarers considered themselves to be tired (cross-shift SSS of all crew members below and above the median age of 37 years: 3.1 vs. 2.6; p= 0.011). Focusing on the group of watchkeeping seafarers, those who were on duty between 00:00-04:00 h and 04:00-08:00 h more often displayed severe sleepiness on duty after their shift (SSS≥ 5) (72.2% and 50.0% respectively).

The 396 pupillometric examinations (15 minutes before and after a shift) revealed that the change in rPUI values during the cross-shift observation did not reach a significant level in intra-individual comparison (mean rPUI before vs. after the working shift: 1.14 vs. 1.19; cross-shift rPUI change: p= 0.355). After stratification, the intra-individual cross-shift change in rPUI values was also not dependent on the occupational groups (Tab. 3), while the different length of working time has to be taken into account.

The objective sleepiness on duty in the study sample was not dependent on age (only a slight tendency for younger seafarers after shift; p= 0.064). During the examination, 12 seafarers fell asleep and therefore were assigned to the group "unfit for duty". The pupillary unrest index in 88 examinations showed the seafarers were "unfit for duty"; additionally "particular attention required" was classified in 110 cases (27.8%). Therefore, only half of the examinations were "normal". No differences were observed in the pupillary unrest index between seafarers with and without watchkeeping duties.

287	In concordance to their subjective self-report in SSS, watchkeepers displayed somewhat	
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- higher rPUI values after the shift than day workers (Tab. 3). The analysis of the correlation of
- the subjective assessment of sleepiness on duty (SSS) with the objective measures of
- 290 pupillometry only revealed a weak correlation after the shift (r= 0.185; p= 0.009).
- 291 Within the group of watchkeepers, stronger sleepiness on duty (rPUI \ge 1.2) after a shift
- 292 lasting from 00:00-04:00 h and from 04:00-08:00 h was observed (75.0% and 55.6%
- 293 respectively).

	Occupation	nal groups		
	Day workers (n=75)	Watchkeepers (n=123)	Crude OR * (95% Cl)	Adjusted OR [#] (95% Cl)
Time periods in the con	text of the current p	oupillometric exami	· ·	(SD)
Sleep period before ¹	5.8 (1.1)	5.5 (1.0)	0.85 (0.78-0.92)	0.88 (0.80-0.95
Working hours examined	9.5 (1.5)	4.9 (1.6)	0.56 (0.43-0.88)	0.57 (0.46-0.92
Subjective stress level of	during examined sh	nift, n (SD)		
Physical ²	48 (64.0%)	78 (63.4%)	0.96 (0.52-1.79)	0.51 (0.24-1.08
Mental ³	41 (54.7%)	94 (76.4%)	2.35 (1.24-4.44)	2.18 (1.08-4.4)
Sleep efficiency ¹				
- Mean (%)	72.7% (11.8%)	67.9% (12.2%)	0.48 (0.26-0.88)	0.48 (0.25-0.9
Stanford Sleepiness Sca	ale (SSS) ⁴, mean (Sl	D)		
Cross-shift⁵	2.6 (1.4)	3.1 (1.7)	0.73 (0.48-1.10)	0.84 (0.55-1.2
Time depending	2.5 (1.4)	2.6 (1.5)	1.07 (0.59-1.95)	0.91 (0.49-7.7)
- Before the shift	2.3 (1.4)	2.0 (1.5)	1.07 (0.39-1.93)	0.91 (0.49-7.70
- After the shift	2.8 (1.4)	3.5 (1.9)	1.81 (1.01-3.25)	1.25 (0.66-2.3
Pupillary unrest index (r PUI) , mean (SD)			
Cross-shift⁵	1.14 (0.66)	1.18 (0.65)	0.92 (0.61-1.40)	1.05 (0.70-1.6
Time depending	1.14 (0.67)	1.12 (0.62)	0.96 (0.52-1.74)	0.86 (0.46-1.6

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1						
2 3 4	- B	efore the shift				
5 6	- A	fter the shift	1.13 (0.66)	1.23 (0.65)	1.55 (0.85-2.84)	1.31 (0.70-2.46)
7 8	Le	vel (n=396) of sleepines		, , ,	· · ·	, , ,
9 10		lone ⁶	78 (52.0%)	120 (48.8%)		
11 12		articular attention		- ()		
13 14		equired ⁷	39 (26.0%)	71 (28.9%)	0.789	
15 16	- U	Infit for duty ⁸	33 (22.0%)	55 (22.3%)		
17	294	*the crude OR bases or	the median of para	meters and include	es differences betwee	en occupational
18 19	295	groups and the examination	ation time of day #a	idjusted for age, ra	nk (officer vs. rating)	and duration of
20 21	296	stay on board at the tim	e of examination			
22 23	297	¹ according to measurer	nents with the armb	and monitor, relate	d to an average 24 h	our period
24	298	² "have you experienced	l physical stress dur	ing the examined s	hift?" ³ "have you ex	perienced
25 26	299	mental stress during the	e examined shift?"			
27 28	300	⁴ SSS-scale from 1 ("fee	el active and vital") u	p to 7 ("almost drea	aming/falling asleep")
29 30	301	⁵ all values exploited (be	efore and after the sl	nift) ⁶ rPUI< 1.02	⁷ rPUI≥ 1.02 and < 1	.53 ⁸ rPUI≥ 1.53
31 32	302	Tab. 3 Cross-shift exan	nination concerning	sleep characteristic	cs	
33 34	303					
35 36	304	Regardless of the occu	national arouns the	objective sleeping	ss on duty (rPLII) did	not
37	305	correlate to the cumulat	•		• • •	
38 39	306	efficiency and the object	·			•
40 41	307	parameters. An associa		. (
42	308	spent on board at the ti				2
43 44	309	stratification according	to the duration of sta	ay on board indicate	es that the associatio	on was
45 46	310	especially true for those	e seafarers with a lo	nger stay on the ve	ssels (pre-shift rPUI	after stay
47	311	of less than 2 months, 2	2-5 months and more	e than 5 months: 1	.06, 1.09 and - much	higher -
48 49	312	1.32). The bivariate gro	uping of the crew ac	cording to their sta	ly of less vs. more th	an 5
50 51	313	months showed signific	ant pre-shift differen	ices in rPUI (1.08 v	rs. 1.32; p= 0.002).	
52 53	314					
54 55						
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59 60				42		
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DISCUSSION

Being a seafarer requires strong mental stability and a robust physical constitution, along with an adaptive and flexible attitude. However, stress and fatigue can hinder maritime professionals in performing effectively.[27] Seafarers spend both their working and leisure time over a couple of months in the restricted shipboard environment that can impact sleep quality and lead to sleepiness.[5] In the present study, a significantly lower sleep efficiency averaging at 69.3% and a higher subjective sleepiness assessment (SSS) after the shift were found among watchkeepers compared to day workers. In addition, the examinations carried out on board objectified critically short durations of the seafarers' sleep average (5.6 h per 24 h) particularly among watchkeepers.

Especially the short sleeping times correspond very well with the results of international studies.[28] Sleep periods on board are often interrupted (potentially due to ship's movements or sudden noise evoked by the handling of containers in harbours).[29] These effects can explain why many seafarers, including day workers, suffer from sleepiness on the high seas. The sleep interruptions are particularly often an inevitable consequence of the watch shift requirements with two 4-h working shifts per day. Thus, on any watch system it is common that seafarers have several sleep episodes per 24-h period. Daytime sleep is usually much less efficient than sleep obtained at the circadian nadir. It can be assumed that some watchkeepers have problems falling asleep after a stressful working day (with scarcely any opportunities for sleep); this results in decreased sleep efficiency. Split sleep among watchkeepers can also not be excluded as the cause of this low sleep efficiency.

Although this study has not proved that sleepiness on duty depends directly on disturbances of the sea during passages, we measured generally low sleep efficiency. This means that not only the amount, but also the quality of sleep is insufficient among the examined seafarers on board. Frequent sleep disruptions can impair alertness to a great degree and consequently lead to an increased risk of accident on board.[30]

Despite similar physical stress levels, the crew members with watchkeeping duties experienced mental stress subjectively more frequently than day workers. This was probably due to their reduced and interrupted sleep time as well as their high job responsibility, which represents a distinct mental stressor. Correspondingly, the watchkeepers starting with a subjective sleepiness level similar to that of the day workers had a significantly more pronounced increase in their sleepiness level after the cross-shift examination. Although no significance level was reached, the cross-shift pupillometry of watchkeepers also indicated a higher level of objective sleepiness after the shift than that of day workers. In this context, the

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1 2		
3	349	difference in the length of examined working time between day workers and watchkeepers
4 5	350	has to be highlighted. The watchkeepers' higher value for SSS and, by trend, for PUI after
6	351	the examined shift is remarkable as they had worked a considerably shorter time than the
7 8 9	352	day workers. Thus, these differences are surely underestimated in this study.
10	353	According to Wilhelm (2008)[31], severe sleepiness is displayed by drivers who did not sleep
11 12	354	during the chronobiologically relevant time frame (0:00 h - 05:00 h). In the maritime setting,
13	355	this especially applies to watchkeepers. These crew members, who are on duty during the
14 15	356	inconvenient time frames between 0:00-04:00 h and 04:00-08:00 h, reported the expected
16 17	357	subjective severe sleepiness, which was also objectively measured using pupillometry. In
18	358	this context, it has to be taken into account that most fatigue-induced shipping disasters take
19 20	359	place in these time frames.[32]
21 22	360	Watchkeepers are habitual shift workers, often experiencing circadian misalignment due to
23	361	their irregular work/rest schedules. This might be one explanation as to why the small
24 25	362	number of available maritime field studies about seafarers' fatigue has exclusively focused
26 27	363	on watchkeepers. Importantly, this study demonstrates that day workers also often
28	364	experience severe sleepiness; more than 20% of both the watchkeepers and the day
29 30	365	workers were characterised as "unfit for duty" during their regular shift and only every second
31	366	pupillary measurement was regarded normal. The fact that 12 seafarers had fallen asleep
32 33	367	during the 11-min pupillary examination and that 35 crew members regarded themselves as
34 35	368	very sleepy post-shift (SSS \geq 6) confirms these alarming pupillometric results. In light of the
36	369	strong impact on the ships' safety, further studies are urgently needed to examine and
37 38	370	counteract the sleepiness of both the shipboard watchkeepers and the day workers.
39 40	371	Furthermore, this study observed that the duration already spent on the vessel at the time of
41	372	the examination correlated with the PUI. This finding could indicate a cumulative effect on the
42 43	373	seafarers' sleepiness. Officers normally have far shorter periods on board than ratings
44 45	374	(averaging 2.5 vs. 4.1 months in a row). Daily sleepiness as a consequence of high work
46	375	strain lasting for many months seems to be plausible. According to the present results,
47 48	376	working periods below five months in a row seem to be reasonable for seafarers. Further
49	377	studies are required to evaluate this hypothesis and to determine recommendations for
50 51	378	maximum working periods on board.
52 53	379	Subjective assessments of sleepiness only displayed a weak correlation with the objective
54 55	380	pupillometric results. This could lead to a misjudgement of the seafarers' current
55 56	381	psychophysical performance, which might also have safety implications. Younger and less
57 58	382	experienced crew members reported more severe sleepiness on duty but did not display
58 59 60	383	differences in their pupillometric measurements. In view of the frequently described high 15

prevalence of fatigue-related accidents in seafaring, a high level of psychophysical stress, but also a misjudgement of their alertness is assumed. Thus, it is recommended to use complementary objective methods besides questionnaires in studies to determine the level of fatigue among examined employees. Future studies should also explore possibilities and evaluate acceptance by the crew to develop more flexible shift scheduling that allows the consideration of circadian preferences and, possibly, individual preferences of the watchkeeping seafarers.

Limitations

The present analysis has some limitations that need to be addressed. Firstly, the sample size of this study is rather small, but in comparison to other available maritime studies the examined seafarer population is far larger. Secondly, the study was carried out in a cross-sectional design that does not allow the evaluation of long-time effects of sleepiness. Due to the permanently changing shipping crews on the vessels, it is hardly possible to arrange long-time follow-up examinations of a noteworthy proportion of seafarers. Thirdly, due to the various occupational and ethnic groups on board, the crews are very heterogeneous and that makes the interpretation and comparison of sleeping behaviours difficult, also when considering the large inter-individual and intra-individual variability in sleep. Fourthly, the present study design does not provide information about the seafarers' sleep architecture. Sleep loss is generally compensated by changing the sleep architecture towards more so-called slow-wave sleep.

The armband monitor used has only a limited informative value about sleep architecture, which is normally measured in sleep laboratories ashore, e.g. using polysomnographic techniques [33]. In maritime field studies, however, the use of such extensive examinations (only one measurement per night) does not appear to be very suitable on board. Furthermore, the determination of lying time with this monitor may be somewhat imprecise so that an underestimation of the sleep efficiency cannot be excluded. In addition, the frequently used sleep diaries for sleep assessment are only subjective procedures and require a survey period of at least 2 weeks, particularly as the shipboard measurements in this study were only to take place during the sea passage.

Moreover, pupillometry has yet not been established as a reliable screening test for sleepiness [34]. Particularly sleep latency or sleep architecture are the domains of extensive examinations in sleep laboratories ashore and were not the focus of the present maritime field study.

Additionally, the PUI correlated with the seafarers' subjective statements. Further studies are

- recommended to evaluate the validity of these devices for their use in maritime field settings as well as to check their suitability on board and their acceptance by the seafarers on the high seas.

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Despite these limitations, the present study analyses for the first time the prevalence of sleepiness in seafarers with and without watchkeeping duties; the findings require further confirmation in a larger cohort. Furthermore, the present maritime field study analysed the prevalence of seafarers' sleepiness on duty by applying various subjective and objective methods. Up to now, most maritime studies about seafarers' sleepiness have not been carried out on board vessels and only rely on subjective methods.[35] Questionnaires are, however, subjective instruments, consequently depending on self-reported data, so that underreporting might have occurred.[36] Additionally, these subjective instruments do not reveal biophysiological differences that might promote the understanding of sleepiness on board.[21,37]

Nowadays, a variety of subjective and objective instruments exist for assessment of excessive daytime sleepiness, including structured sleep history, sleep logs and sleep questionnaires. The multiple sleep latency test, for example, is often used as an objective measurement to evaluate sleep propensity. However, in view of the large overlap between healthy subjects and subjects with sleep disorders, its use to assess sleepiness is questionable. Furthermore, its results are often jeopardised by motivational influences and the last nap effect.[35] Consequently, a feasible and convenient method that is less dependent on motivation - such as the pupillometry used in this study - seems to constitute an enrichment in field studies.[21]

35 438

37 439 Implications for clinicians and policy makers

Fatigue in the maritime setting could be counteracted by strict compliance with and monitoring of the obligatory rest and sleep times. According to Allen, Wadsworth et al. (2007)[35], it is not uncommon in seafaring for legal obligations to be neglected, for example by ignoring the minimum safety levels for crewing on board. To reduce the seafarers' workload on board during the vessel's stay in port, some job duties could be transferred to land-based workers ashore. In light of the frequently observed sleepiness on duty within the study sample, training should be offered for shipboard crews to improve sleep hygiene and techniques to support short-term relaxation, such as power napping. This training should be accompanied by the strengthening of the seafarers' individual resources (e.g. training to cope with stress for

 $_{54}^{55}$ 449 health promotion) to enable them to compensate for the inevitable psychophysical strain on

- ⁵⁵ 450 board. Considering the present results, limiting the work periods of seafarers (perhaps to a
- 57 451 maximum of five months) might be an essential preventive measure in a maritime setting.

2		
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30	468	paper for publication.
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33	469	
34 35	470	Conflict of interest
36	471	Both authors declare no conflicts of interest.
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40 41	473	Patient consent
42	474	Patient consent Not required.
43 44	474	Not required.
45	475	
46 47	476	Ethics approval
48		
49 50	477	The study was approved by the Ethics Committee of the Hamburg Medical Association (no.
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52 53	479	
54	480	Data sharing statement
55 56	400	Bata sharing statement
57	481	No additional data are available.
58 59	482	
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	Item No	Recommendation	Pag No
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used term in the title or the abstract	1
		(<i>b</i>) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5,7
Participants	6	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants	5,6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7,8
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	7,8
measurement		assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	
		(<i>d</i>) If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	
Results			
Participants	13*	 (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed 	9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted	10-
		estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12

		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias	15
		or imprecision. Discuss both direction and magnitude of any potential bias	16
Interpretation	20	Give a cautious overall interpretation of results considering objectives,	15
		limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Sleepiness of day workers and watchkeepers on board at high seas: a cross-sectional study

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6 7		
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17 ABSTRACT

18 Objectives

To estimate the prevalence of sleepiness on duty among day workers and watchkeepers onboard.

21 Design

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22 Cross-sectional survey in a maritime field study.

23 Setting

24 10 shipping companies with container vessels under German management.

25 Participants

The whole crew (75 day workers and 123 watchkeepers) during 18 voyages on 18 different container ships.

28 Outcome measures

⁷ 29 Sleepiness on duty and efficiency of sleep using pupillometry (in a cross-shift design) and the
 ⁸ 30 SenseWear® armband activity monitor.

31 Results

The watchkeepers showed significantly shorter sleep periods than day workers (5.5 h vs. 5.8 h). The average efficiency of sleep was 69.6% and significantly lower among watchkeepers (OR 0.48; 95% CI 0.26-0.88). 396 pupillometric examinations were carried out and revealed 88 study members (22.2%) with a pupillary unrest index (rPUI) in a range characterised as "unfit for duty" and 110 seafarers (27.8%) categorised as "particular attention required". The average rPUI was similar between day workers and watchkeepers. The Epworth Sleepiness Scale revealed recent daytime sleepiness in 70 seafarers, which

- 39 was similarly often stated by day workers and watchkeepers. Based on the Stanford
- 40 Sleepiness Scale (SSS), a measurable cross-shift increase in the SSS value during the
- $\frac{1}{8}$ 41 examined shift was observed, especially among watchkeepers. The amount of time already
- ¹⁹ 42 spent on the vessel at the time of the present examination was significantly associated with
 - 43 the rPUI (p= 0.009).

44 Conclusion

45 Sleep periods of both the day workers and the watchkeepers aboard vessels were alarmingly

- 46 short and sleep efficiency was low. Sleepiness on duty is similarly prevalent among day
- ³ 47 workers and watchkeepers and seems to depend partly on the cumulative working period on
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3	48	the vessels. Preventive measures need to be taken by the shipping industry to counteract
4 5	49	fatigue (e.g.by enabling sufficient rest and sleep times).
6 7	50	
8 9	51	Key words: occupational medicine, sleepiness, seafaring, pupillometry
10 11	52	
12 13		Strongthe and limitations of this study
14	53	Strengths and limitations of this study
15 16	54	The present maritime field study shows for the first time the prevalence of seafarers'
17	55	sleepiness on duty during the sea passage, drawing a distinction between crew members
18 19	56	with and without watchkeeping duties.
20	57	The present study analysed seafarers' sleepiness on duty by applying both subjective and
21 22	58	objective methods that are less dependent on the participants' motivation (pupillometry,
22	59	armband activity monitor).
24 25	60	The study was carried out in a cross-sectional design that does not allow evaluation of
26	61	long-time effects of sleepiness.
27 28	62	> Due to the various occupational groups on board, the crews are very heterogeneous; that
29 30	63	makes the interpretation and comparison of sleeping behaviours difficult.
31	64	
32 33 34	65	INTRODUCTION
35 36	66	Long and irregular working hours each day, combined with sleep deficiency and long periods
37	67	of work at sea, are crucial risk factors for increased sleepiness on duty among seafarers.[1,2]
38 39	68	Strong weather conditions can also affect seafarers' performance, increase the risk of error
40 41	69	and, consequently, cause injuries or fatalities to personnel. Psychological strain in maritime
42	70	professions can also lead to psychosomatic diseases including burnout syndrome or
43 44	71	exhaustion.[3] Some studies have stated that shipping crews suffer from psychophysical
45 46	72	exhaustion/strain due to stress and decreased periods and quality of sleep.[4] Thus, seafaring
46 47	73	still ought to be considered a high-risk profession for psychophysical exhaustion.[5,6]
48 49		
50	74	Three voyage episodes can be distinguished on board: stays in port, river passages and sea
51 52	75	passages. During the first two voyage episodes, the seafarers are often exposed to high
53	76	psychophysical stressors caused by unforeseeable and external demands that possibly need to
54 55	77	be addressed at chronobiologically adverse times (e.g. embarkation and disembarkation,
56	78	loading and unloading, exchange of information with port authorities). During the sea passage,
57 58	79	the engine room personnel, the electricians and the galley staff can often adhere to a regular
59 60	80	working day of 8 hours (day workers). This is better suited to chronobiologically adapted sleep 3

periods and can thus partially compensate for a potential sleep deficiency.[7] In contrast, due to obligatory navigation manoeuvres, nautical officers and a large number of the deck ratings are often required to work in a 24-hour shift system during sea passages (watchkeepers).

Nowadays, merchant ships operating internationally generally run on a 4/8-hour watch shift system. That means that three nautical officers alternate in a system which includes four hours on duty and eight hours off for each of them. Van Leeuwen, Kircher et al. (2013)[8] measured the effect of a 4/8-hour watch shift system on the alertness of seafarers in a ship simulator. They observed that especially additional overtime was associated with a subjective and objective increase in sleepiness. The authors also showed sleepiness increasing with time on watch and peaking at the end of a watch.

It has been described that watchkeeping, critical assignments during night time and irregular working periods can lead to disruptions of the crews' circadian rhythm as a precondition for sleepiness on board.[9] Dohrmann and Leppin (2017)[7] performed a systematic analysis and quality assessment of seafarers' fatigue. They observed that working nights was most fatiguing and that fatigue levels were higher toward the end of a watch or shift. According to the review, particularly the psychosocial work environment (including day workers besides the watchkeepers) had received little attention. However, the monotonous noise of the vessel's engine, the smooth ship's vibrations and the continuous slow ship's movements (during calm weather conditions) can lead to sleepiness of the whole crew on board. Higher levels of exposure to noise and vibrations can also increase sleep troubles/problems and poorer sleep guality when impacting on employees throughout the day.[10]

Working in a maritime setting is characterised by a wide variety of occupations with numerous fatiguing physical and mental strains, depending on the type of job.[11] The available maritime fatigue studies have only focused on watch officers as crew members who typically also work during night hours.[2,8,12,13] Thus, there is a lack of knowledge about sleepiness on the high seas among the other shipboard occupational groups, including the day workers. Knowing who is affected by severe sleepiness on board is of great importance to facilitate its prevention.

The present maritime field study analysed for the first time the prevalence of seafarers' sleepiness on duty during the sea passage, with a distinction between day workers and watchkeepers on board.

112 METHODS

113 Study sample

A medically trained scientist accompanied 18 sea voyages on 18 different container ships operating in the Baltic Sea and examined the crew members on board. 206 out of 225 seafarers took part in the study (response rate 91.6%). Only the results of those 198 seafarers were included who could be interviewed and examined (pupillometry) in a cross-shift design (both before the beginning and after the end of their shift). Taking part in this study was voluntary and the individual data was pseudonymised. No patients were involved in this study. All participants gave their written informed consent before taking part in this study. The study was approved by the Ethics Committee of the Hamburg Medical Association (no PV4395).

The 198 seafarers were classified into two occupational groups (75 day workers and 123 watchkeepers) (Tab. 1). The median age of the exclusively male study sample was 36.7 years (19 - 67 years) and significantly higher among the day workers. Furthermore, the day workers had a somewhat higher body weight than the watchkeepers. No differences were observed in the circadian preference when comparing watchkeepers with day workers. The difference between the two occupational groups in terms of their marital status and the presence of children was not noteworthy. 49.0% of the seafarers either smoked or were former smokers.

37 131

132 Patient and Public Involvement 39

The present study focused on the sleepiness of shipboard crews; patients and/or public were not the target group of this study. Previous studies revealed that sleepiness constitutes one of the major problems amongst seafarers. All German shipping companies owning container ships were invited to participate in this study. 10 shipping companies agreed and put 18 different container ships at our disposal (the proportion of ships was four times one, four times two and twice three vessels per shipping company).

All seafarers on board of these vessels were informed about our study design, aim and
 All seafarers on board of these vessels were informed about our study design, aim and
 content and were encouraged to participate (participation rate 88.0%). After completion of
 our board examination, an individual medical report was created and sent to each of the
 accepting seafarers to their home address.

2 3			Devenerkere	Matabkaanava
4			Day workers	Watchkeepers
5			(54 engine room personnel,	(46 nautical officers, 77
6 7 8			16 electricians, 5 galley staff)	deck ratings)
9 10		Number; n (%)	75 (37.9%)	123 (62.1%)
11 12 13 14		Age ; median years (min- max)	44 (19-67)	35 (19-63)
15 16 17		BMI; median (min-max)	26 (19-40)	24 (17-36)
18 19 20		Morning-Evening-Question	nnaire, n (%)	
21 22		Morning type	45 (60.0%)	68 (55.2%)
23 24 25		Intermediate type	24 (32.0%)	46 (37.4%)
26 27		Evening type	6 (8.0%)	9 (7.4%)
28 29 30		Origin ; n (%)		
31 32		European	38 (50.7%)	47 (38.2%)
33 34 35		Southeast Asian	37 (49.3%)	76 (61.8%)
36 37		Married; n (%)	53 (70.7%)	87 (70.7%)
38 39		Children; n (%)	53 (70.7%)	82 (66.7%)
40 41 42		Smoking status; n (%)		
43 44		Never smoked	36 (48.0%)	65 (52.8%)
45 46 47		Former smoker/smoker	39 (52.0%)	58 (47.2%)
48 49	144	Tab. 1 Demographic and life	estyle parameters by occupationa	l groups on board
50 51	145			
52 53	146	To assess long-term effects	on sleep during their current peri	od on board, the participants
54 55	147	were additionally grouped in	respect of their stay on board at	the time of examination (< 2
55 56 57	148	months, 2-5 months and > 5	months).	
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50 **Examination procedure**

All seafarers taking part in the study were examined with the SenseWear® armband monitor and pupillometry both during shifts and during time off (including sleep time). These devices were selected because they did not considerably disturb the crew's daily routines (low weight, no cable connection, easy use), which was a precondition. The present study monitored the sleep of all seafarers in a continuous mode during a period of at least 72 hours of observation. An observation time of at least 3 days during the sea passage was chosen because of the known variations of sleep quality on a daily basis.

The average period of wearing the armband monitor was 66.3 h (SD 14.8 h) (>92% of
observation time) and did not differ between the occupational groups. The pupillometric
examination took place within this observation period.

162 Efficiency of sleep

The SenseWear® armband activity monitor is a device that weighs 82 g and is worn on the right upper arm just above the triceps muscle according to its validation requirements. While wearing the armband monitor, the seafarers could easily operate the device for themselves without support from the shipboard examiner. The monitor is designed to analyse the profile of physical activity (movement, lying down or sleeping). The collected information allows the estimation of sleep efficiency by establishing the ratio of the duration of sleep and the time spent lying down. Thus, efficiency of sleep expresses the time spent actually sleeping while lying down.

171 The armband monitor has already been successfully applied in many studies as a detector of
 172 sleep.[14-19] Current studies reveal that the total sleep time and time in bed correlate
 173 significantly between the measurements of the armband monitor and the polysomnography
 174 (p<0.001); the armband has proved to be superior in comparison to other commercially
 175 available activity monitors.[16]

177 **Pupillometry**

178 The device *Fit-For-Duty* by AmTech was used to conduct pupillometric examinations [20].

- ¹⁶ 179 The Pupillographic Sleepiness Test is considered an objective method for documenting
 - 180 sleepiness by monitoring spontaneous and unconscious oscillations of the pupil without

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stimulating light. The result is a pupillogram, which can be used to deduct the pupillary unrest index (rPUI). This parameter therefore is an objective measure for the variance of the diameter of the pupil. A recent study suggested the Pupillographic Sleepiness Test as a reliable measurement for detecting drowsiness-related impairment.[21]

The rPUI is compared to standard values. Results < 1.02 are considered normal. "Particular attention required" is the characterisation of results \geq 1.02 and < 1.53. An index \geq 1.53 is rated as "unfit for duty". This methodology has repeatedly been used in scientific studies to assess sleepiness.[22-24]

During a sea passage, the pupillometric examination was performed twice according to a cross-shift design for all 198 seafarers included in the study sample. The chosen sea passages lasted for at least 24 hours and therefore allowed a regular operation of the vessel and predictable working procedures. The pupillometric cross-shift examination took place 15 minutes before the respective shift started and directly after it ended so that that shift was neither shortened nor disturbed by this examination. In general, it is not likely that the seafarers were distinctly disturbed by the examination with the chosen devices or by the presence of the medical staff on board.

The engine room personnel, the electricians and the galley staff (without watchkeeping duties) were examined during an average work shift that lasted 8 hours (most likely from 8:00 h to 17:00 h including a lunch break of 1 hour). As watchkeepers have two work units per day -each of them about 4 h (six shift periods: 0-4 h, 4-8 h, 8-12 h, 12-16 h, 16-20 h and 20-24 h) - a split sleeping time is often observed in this occupational group. The watchkeepers were examined during a randomly selected shift period with the aim of achieving an equal representation of these periods (about 20 watchkeepers/shift period). For the assessment of cross-shift reactions, it was unavoidable to compare the PUI and SSS between two occupational groups with different lengths of working times.

Questionnaire

In the framework of a standardised interview, all seafarers were asked about their demographic data, their subjective physical and mental stress level, their sleep period before the examined shift and their current working time. Additionally, daytime sleepiness was estimated by using the Epworth Sleepiness Scale. [25]. This is a self-administered questionnaire which is shown to provide a measurement of the subject's general level of daytime sleepiness. Retrospectively, the probability of nodding off or falling asleep in eight

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typical everyday situations is investigated. Furthermore, the Stanford Sleepiness Scale was 4 used as a self-rating scale to quantify progressive stages of sleepiness.[26] Individual 5 circadian fluctuations in sleepiness and alertness can be determined through repetition in 6 7 intervals. In the present study, this scale assessed the sleepiness before and after a shift. 8 Finally, the seafarers filled in the Morning-Evening-Questionnaire (rMEQ) for the assessment 9 of the circadian preference.[27, 28] This questionnaire evaluates against individual differences 0 in the circadian rhythm. Responses to the questions are combined to form a composite score that indicates the degree to which the respondent favours morning versus evening. 1

223 Statistics

Statistic analysis was performed with SPSS (version 24, IBM Corporation). The Shapiro-Wilk 4 5 test was used to test for normal distribution of data. Where variables were not normally distributed, non-parametric tests (Mann Whitney-U test, Wilcoxon test) were used. The Chi-6 7 squared test was applied to analyse differences in frequencies of parameters. Crude odds 8 ratio (OR) including 95% confidence intervals was calculated by binary logistic regression. 9 For adjustment reasons, age, rank (officer vs. rating), the examination time of day and duration of stay on board at the time of examination were added. Furthermore, correlations 0 were analysed by using the Spearman test. 1

All indicated p-values were two-sided, and a p-value of < 0.05 was regarded as statisticallysignificant.

235 **RESULTS**

The number of months day workers had already spent on the vessel at the time of examination and during their current contract was similar to that of watchkeepers. In particular, the stratification of the seafarers in tertiles concerning their recent stay on board did not reveal any differences (Tab. 2).

The Epworth Sleepiness Scale (ESS) showed that 70 seafarers (35.4%) had recently been suffering from daytime sleepiness. The ESS value increased significantly (p= 0.004) with the length of stay on board. No differences were observed when differentiating according to the obligation to perform watchkeeping duties (p= 0.113). Younger seafarers below the age median of 37 years indicated daytime sleepiness more often than older colleagues (p= 0.014).

1 2 3			0		
4 5				pational groups	
6 7			Day workers	Watchkeepers	p
8			(n=75)	(n=123)	
9 10		Stay on board			
11 12		At the time of examination;	0 (4 40)		0.007*
13		median months (min-max)	3 (1-12)	3 (0-11)	0.837*
14 15		Frequency according to			
6 7		tertile; n (%)			
8			00 (07 00()		
19 20		≤ 2 months	28 (37.3%)	45 (36.6%)	
21		> 2 and \leq 5 months	28 (37.3%)	45 (36.3%)	0.973#
22 23		> 5 months	19 (25.3%)	33 (26.8%)	
24 25		Scheduled (min-max)	7 (2-13)	8 (1-12)	0.719*
26				0 (1-12)	0.710
.7 .8		Epworth Sleepiness Scale (ESS),	, median (min-max)		
9 0		Score value (SD) ¹	8 (0-15)	8 (0-21)	0.113*
1		≥ Cut off value (10), n (%)	26 (34.7%)	44 (35.8%)	0.875#
2 3	245	*Mann Whitney-U test #Chi-square	ed test ¹ sleepiness scale	from 0 ("no chance to doze	e in")
4 5	246	up to 24 ("maximum chance to doz	e in")		
6	247	Tab. 2 Stay on board and subjectiv	e assessment for davtime	sleepiness	
57 18	217			0.0000000	
9 0	248				
1	249	Cross-shift examinations			
2 3					
•	250	To analyse the recent alertness attr			
-6	251	to participate in a cross-shift examined	-		
8	252	the cumulative sleep time before th			d for
9	253	5.6 hours (SD 1.0) per 24 h period,			
1	254	durations compared to the day workers (Tab. 3). The working hours during the examined			
2	255	shift were significantly lower amongst watchkeepers. Concerning their subjective stress level			
4	256	during the shift examined, significantly more watchkeepers experienced mental demands			
6	257	than day workers (OR 2.35; 95% CI 1.24-4.44). After adjustment for age, ranking,			
7	258	examination time of day and recent		•	
8 9	259	elevated risk for mental stress rema	ained significant among wa	atchkeepers.	
60			10		

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1 2		
3	260	During the examined shift, the average sleep efficiency was 69.3% and was significantly
4 5	261	lower among watchkeeping seafarers than day workers (OR 0.48; 95% CI 0.26-0.88). This
6 7	262	finding was independent of the age, ranking, time of day of the examination and the recent
8	263	duration of shipboard stay. 63.7% of the participating seafarers stated that they had
9 10	264	consumed coffee within the past 4 hour before our pupillometric examination on board
11	265	irrespective of their occupational group.
12 13	266	Defens their shift, the mean value on the Otenferd Olessians Ocels (OOO) was O.C. (OD. 1.4)
14 15	266	Before their shift, the mean value on the Stanford Sleepiness Scale (SSS) was 2.6 (SD 1.4)
15 16	267	(2= "functioning at high levels, but not fully alert"; 3= "awake, but relaxed; responsive but not
17	268	fully alert"); after the work shift, the level of sleepiness was significantly higher (3.2 (SD 1.8))
18 19	269	(Wilcoxon test: p= 0.001) indicating a measurable increase in the subjective sleepiness in the
20	270	course of a shift. This was especially true for watchkeepers although the length of their
21 22	271	working time was much shorter than that of day workers (Tab. 3). Consequently, more
23 24	272	watchkeepers reported current sleepiness than day workers after the examined shift.
25	273	A remarkable number of 35 seafarers (17.7%) reported a level of sleepiness on duty of 6/7
26 27	274	on the SSS (6= "sleepy, woozy, fighting sleep, prefer to lie down"; 7= "no longer fighting
28	275	sleep; sleep onset soon; having dream-like thoughts") after their shift. According to SSS,
29 30	276	more young seafarers considered themselves to be tired (cross-shift SSS of all crew
31 32	277	members below and above the median age of 37 years: 3.1 vs. 2.6; p= 0.011). Focusing on
33	278	the group of watchkeeping seafarers, those who were on duty between 00:00-04:00 h and
34 35	279	04:00-08:00 h more often displayed severe sleepiness on duty after their shift (SSS≥ 5) (72.2%
36	280	and 50.0% respectively).
37 38		2
39	281	The 396 pupillometric examinations (15 minutes before and after a shift) revealed that the
40 41	282	change in rPUI values during the cross-shift observation did not reach a significant level in
42 43	283	intra-individual comparison (mean rPUI before vs. after the working shift: 1.14 vs. 1.19; cross-
43 44	284	shift rPUI change: p= 0.355). After stratification, the intra-individual cross-shift change in rPUI
45 46	285	values was also not dependent on the occupational groups (Tab. 3), while the different length
40 47 48	286	of working time has to be taken into account.
49	287	The objective sleepiness on duty in the study sample was not dependent on age (only a
50 51	288	slight tendency for younger seafarers after shift; p= 0.064). During the examination, 12
52	289	seafarers fell asleep and therefore were assigned to the group "unfit for duty". The pupillary
53 54	290	unrest index in 88 examinations showed the seafarers were "unfit for duty"; additionally
55 56	291	"particular attention required" was classified in 110 cases (27.8%). Therefore, only half of the
56 57	292	examinations were "normal". No differences were observed in the pupillary unrest index
58 59	293	between seafarers with and without watchkeeping duties.
60		11

2	294	In concordance to the	oir subjective self-ren	ort in SSS watchkee	eners displayed som	ewhat	
4		In concordance to their subjective self-report in SSS, watchkeepers displayed somewhat					
5	295	higher rPUI values after the shift than day workers (Tab. 3). The analysis of the correlation of					
6 7	296	the subjective assess	ment of sleepiness of	on duty (SSS) with th	e objective measure	s of	
8 9	297	pupillometry only reve	pupillometry only revealed a weak correlation after the shift (r= 0.185; p= 0.009).				
10 11	298	Within the group of w	atchkeepers, strong	er sleepiness on duty	v (rPUI ≥ 1.2) after a	shift	
12	299	lasting from 00:00-04	:00 h and from 04:00	0-08:00 h was observ	red (75.0% and 55.6	%	
13 14	300	respectively).					
15 16	301						
17 18 19			Occupation	nal arouns			
20				•			
21			Day workers	Watchkeepers	Crude OR*	Adjusted OR [#]	
22 23			(n=75)	(n=123)	(95% CI)	(95% CI)	
23 24						(22)	
25	lin	ne periods in the cont	ext of the current p	oupillometric exami	nation, mean hours	(SD)	
26 27		Sleep period before ¹	5.8 (1.1)	5.5 (1.0)	0.85 (0.78-0.92)	0.88 (0.80-0.95)	
27 28							
29	,	Working hours					
30		examined	9.5 (1.5)	4.9 (1.6)	0.56 (0.43-0.88)	0.57 (0.46-0.92)	
31 32							
33	Su	bjective stress level d	uring examined sh	ift, n (SD)			
34		-	U				
35		Physical ²	48 (64.0%)	78 (63.4%)	0.96 (0.52-1.79)	0.51 (0.24-1.08)	
36 37						0 40 (4 00 4 40)	
38		Mental ³	41 (54.7%)	94 (76.4%)	2.35 (1.24-4.44)	2.18 (1.08-4.40)	
39							
40	Sle	ep efficiency ¹					
41 42 43	- M	lean (%)	72.7% (11.8%)	67.9% (12.2%)	0.48 (0.26-0.88)	0.48 (0.25-0.91)	
44 45	Sta	anford Sleepiness Sca	ıle (SSS) ⁴, mean (SI	D)			
46 47	Cro	oss-shift⁵	2.6 (1.4)	3.1 (1.7)	0.73 (0.48-1.10)	0.84 (0.55-1.29)	
48 49	Tin	ne depending	2.5 (1.4)	2.6 (1.5)	1.07 (0.59-1.95)	0.91 (0.49-7.70)	
50 51	- B	efore the shift	2.5 (1.4)	2.0 (1.3)	1.07 (0.00-1.00)	0.01 (0.40-1.10)	
52 53	- A	fter the shift	2.8 (1.4)	3.5 (1.9)	1.81 (1.01-3.25)	1.25 (0.66-2.37)	
54 55 56	Pu	pillary unrest index (r	PUI) , mean (SD)				
50 57	Cro	oss-shift⁵	1.14 (0.66)	1.18 (0.65)	0.92 (0.61-1.40)	1.05 (0.70-1.61)	
58							
59							

1 2 3	Tin	ne depending					
4 5		efore the shift	1.14 (0.67)	1.12 (0.62)	0.96 (0.52-1.74)	0.86 (0.46-1.61)	
6 7 8 9 10	- After the shift		1.13 (0.66)	1.23 (0.65)	1.55 (0.85-2.84)	1.31 (0.70-2.46)	
	Lev	vel (n=396) of sleepines	s on duty⁵n (%)				
11 12	- N	one ⁶	78 (52.0%)	120 (48.8%)			
13 14 15	- Particular attention required ⁷		39 (26.0%)	71 (28.9%)	0.789		
16 17	- U	nfit for duty ⁸	33 (22.0%)	55 (22.3%)			
18 19	302	*the crude OR bases or	n the median of para	x	es differences betwe	en occupational	
20 21	303	groups and the examin	ation time of day #a	djusted for age, ra	ank (officer vs. rating)	and duration of	
22	304	stay on board at the tin	ne of examination		-		
23 24	305	¹ according to measure	ments with the armba	and monitor, relate	ed to an average 24 h	our period	
25 26	306	² "have you experienced	d physical stress duri	ng the examined	shift?" ³"have you e>	kperienced	
27 28 29	307	mental stress during the examined shift?"					
29 30	308	⁴ SSS-scale from 1 ("fee	el active and vital") u	p to 7 ("almost dre	aming/falling asleep")	
31 32	309	⁵ all values exploited (be	efore and after the sh	nift) ⁶ rPUI< 1.02	⁷ rPUI≥ 1.02 and < 1	.53 ⁸ rPUI≥ 1.53	
32 33 34	310	Tab. 3 Cross-shift exar	mination concerning	sleep characterist	ics		
35 36	311						
37 38	312	Regardless of the occu	pational groups, the	objective sleepine	ess on duty (rPUI) did	not	
39 40	313	correlate to the cumula	tive sleep over a 24-	h period before th	e examined shift, the	sleep	
41	314	efficiency and the object	ctive assessment of t	he ship's motion a	according to the ship's	s journal	
42 43	315	parameters. An associa	ation was observed,	however, betweer	the duration of time	already	
44	316	spent on board at the ti	me of the seafarers'	examination and	the rPUI (p= 0.009). 1	Гһе	
45 46	317	stratification according	to the duration of sta	y on board indica	tes that the association	on was	
47 48	318	especially true for those	e seafarers with a lor	nger stay on the v	essels (pre-shift rPUI	after stay	
49	319	of less than 2 months,	2-5 months and more	e than 5 months: ´	1.06, 1.09 and - much	ı higher -	
50 51	320	1.32). The bivariate gro	ouping of the crew ac	cording to their st	ay of less vs. more th	an 5	
52	321	months showed signific	ant pre-shift differen	ces in rPUI (1.08	vs. 1.32; p= 0.002).		
53 54 55 56 57	322						
58 59 60				13			

323 DISCUSSION

Being a seafarer requires strong mental stability and a robust physical constitution, along with an adaptive and flexible attitude. However, stress and fatigue can hinder maritime professionals in performing effectively.[29] Seafarers spend both their working and leisure time over a couple of months in the restricted shipboard environment that can impact sleep quality and lead to sleepiness.[5] In the present study, a significantly lower sleep efficiency averaging at 69.3% and a higher subjective sleepiness assessment (SSS) after the shift were found among watchkeepers compared to day workers. In addition, the examinations carried out on board objectified critically short durations of the seafarers' sleep average (5.6 h per 24 h) particularly among watchkeepers.

Especially the short sleeping times correspond very well with the results of international studies.[30] Sleep periods on board are often interrupted (potentially due to ship's movements or sudden noise evoked by the handling of containers in harbours).[31] These effects can explain why many seafarers, including day workers, suffer from sleepiness on the high seas. The sleep interruptions are particularly often an inevitable consequence of the watch shift requirements with two 4-h working shifts per day. Thus, on any watch system it is common that seafarers have several sleep episodes per 24-h period. Daytime sleep is usually much less efficient than sleep obtained at the circadian nadir. It can be assumed that some watchkeepers have problems falling asleep after a stressful working day (with scarcely any opportunities for sleep); this results in decreased sleep efficiency. Split sleep among watchkeepers can also not be excluded as the cause of this low sleep efficiency.

Although this study has not proved that sleepiness on duty depends directly on disturbances of the sea during passages, we measured generally low sleep efficiency. This means that not only the amount, but also the quality of sleep is insufficient among the examined seafarers on board. Frequent sleep disruptions can impair alertness to a great degree and consequently lead to an increased risk of accident on board.[32]

Despite similar physical stress levels, the crew members with watchkeeping duties experienced mental stress subjectively more frequently than day workers. This was probably due to their reduced and interrupted sleep time as well as their high job responsibility, which represents a distinct mental stressor. Correspondingly, the watchkeepers starting with a subjective sleepiness level similar to that of the day workers had a significantly more pronounced increase in their sleepiness level after the cross-shift examination. Although no significance level was reached, the cross-shift pupillometry of watchkeepers also indicated a higher level of objective sleepiness after the shift than that of day workers. In this context, the

3	357	difference in the length of examined working time between day workers and watchkeepers
4 5	358	has to be highlighted. The watchkeepers' higher value for SSS and, by trend, for PUI after
6 7	359	the examined shift is remarkable as they had worked a considerably shorter time than the
, 8 9	360	day workers. Thus, these differences are surely underestimated in this study.
10	361	According to Wilhelm (2008)[33], severe sleepiness is displayed by drivers who did not sleep
11 12	362	during the chronobiologically relevant time frame (0:00 h - 05:00 h). In the maritime setting,
13 14	363	this especially applies to watchkeepers. These crew members, who are on duty during the
14	364	inconvenient time frames between 0:00-04:00 h and 04:00-08:00 h, reported the expected
16 17	365	subjective severe sleepiness, which was also objectively measured using pupillometry. In
18	366	this context, it has to be taken into account that most fatigue-induced shipping disasters take
19 20	367	place in these time frames.[34]
21 22	368	According to the results of the Morning-Evening-Questionnaire in the present study, the
23 24	369	morning type was overrepresented in the study group. Due to the fact that their work shifts
24 25	370	on board often begin early in the morning over several months in a stretch, many seafarers
26 27	371	are surely adapted to this daily rhythm and subjectively feel particularly fit in the early
28	372	morning-hours. This is a hypothesis for the skewed distribution towards the morning type in
29 30	373	our study that needs confirmation in further field studies on board.
31 32	374	Watchkeepers are habitual shift workers, often experiencing circadian misalignment due to
33	375	their irregular work/rest schedules. This might be one explanation as to why the small
34 35	376	number of available maritime field studies about seafarers' fatigue has exclusively focused
36 37	377	on watchkeepers. Importantly, this study demonstrates that day workers also often
38	378	experience severe sleepiness; more than 20% of both the watchkeepers and the day
39 40	379	workers were characterised as "unfit for duty" during their regular shift and only every second
41	380	pupillary measurement was regarded normal. The fact that 12 seafarers had fallen asleep
42 43	381	during the 11-min pupillary examination and that 35 crew members regarded themselves as
44 45	382	very sleepy post-shift (SSS \geq 6) confirms these alarming pupillometric results. In light of the
43 46	383	strong impact on the ships' safety, further studies are urgently needed to examine and
47 48	384	counteract the sleepiness of both the shipboard watchkeepers and the day workers.
49 50	385	Furthermore, this study observed that the duration already spent on the vessel at the time of
51	386	the examination correlated with the PUI. This finding could indicate a cumulative effect on the
52 53	387	seafarers' sleepiness. Officers normally have far shorter periods on board than ratings
54 55	388	(averaging 2.5 vs. 4.1 months in a row). Daily sleepiness as a consequence of high work
55 56	389	strain lasting for many months seems to be plausible. According to the present results,
57 58	390	working periods below five months in a row seem to be reasonable for seafarers. Further
59 60		15

391 studies are required to evaluate this hypothesis and to determine recommendations for392 maximum working periods on board.

Subjective assessments of sleepiness only displayed a weak correlation with the objective pupillometric results. This could lead to a misjudgement of the seafarers' current psychophysical performance, which might also have safety implications. Younger and less experienced crew members reported more severe sleepiness on duty but did not display differences in their pupillometric measurements. In view of the frequently described high prevalence of fatigue-related accidents in seafaring, a high level of psychophysical stress, but also a misjudgement of their alertness is assumed. Thus, it is recommended to use complementary objective methods besides questionnaires in studies to determine the level of fatigue among examined employees. Future studies should also explore possibilities and evaluate acceptance by the crew to develop more flexible shift scheduling that allows the consideration of circadian preferences and, possibly, individual preferences of the watchkeeping seafarers.

26 405

406 Limitations

The present study has some limitations that need to be addressed. Firstly, the sample size of this study is rather small, but in comparison to other available maritime studies the examined seafarer population is far larger. Secondly, the study was carried out in a cross-sectional design that does not allow the evaluation of long-time effects of sleepiness. Due to the permanently changing shipping crews on the vessels, it is hardly possible to arrange long-time follow-up examinations of a noteworthy proportion of seafarers. Thirdly, due to the various occupational groups on board, the crews are very heterogeneous and that makes the interpretation and comparison of sleeping behaviours difficult, also when considering the large inter-individual and intra-individual variability in sleep. Fourthly, the present study design does not provide information about the seafarers' sleep architecture. Sleep loss is generally compensated by changing the sleep architecture towards more so-called slow-wave sleep.

The armband monitor used is mainly suitable for measuring bed rest[35] and has only a limited informative value about sleep architecture, which is normally measured in sleep laboratories ashore, e.g. using polysomnographic techniques.[36] In maritime field studies, however, the use of such extensive examinations (only one measurement per night) does not appear to be very suitable on board. Furthermore, the determination of lying time with this monitor may be somewhat imprecise so that an underestimation of the sleep efficiency cannot be excluded. Although the sleep diaries frequently used for sleep assessment are only subjective procedures,

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3	425	in further studies the armband monitor examination should be accompanied by the use of sleep
4 5	426	diaries as they allow checking the start and end times of sleep.
6 7	427	Moreover, pupillometry has yet not been established as a reliable screening test for sleepiness
8	428	[36]. Particularly sleep latency or sleep architecture are the domains of extensive examinations
9 10	429	in sleep laboratories ashore and were not the focus of the present maritime field study.
11	430	Additionally, the PUI correlated with the seafarers' subjective statements. Further studies are
12 13	431	recommended to evaluate the validity of these devices for their use in maritime field settings as
14 15	432	well as to check their suitability on board and their acceptance by the seafarers on the high seas.
16 17	433	Despite these limitations, the present study analyses for the first time the prevalence of
18	434	sleepiness in seafarers with and without watchkeeping duties; the findings require further
19 20	435	confirmation in a larger cohort. Furthermore, the present maritime field study analysed the
21 22	436	prevalence of seafarers' sleepiness on duty by applying various subjective and objective
23	437	methods. Up to now, most maritime studies about seafarers' sleepiness have not been carried
24 25	438	out on board vessels and only rely on subjective methods.[37] Questionnaires are, however,
26	439	subjective instruments, consequently depending on self-reported data, so that underreporting
27 28	440	might have occurred.[38] Additionally, these subjective instruments do not reveal
29	441	biophysiological differences that might promote the understanding of sleepiness on
30 31 32	442	board.[21,39]
33 34	443	Nowadays, a variety of subjective and objective instruments exist for assessment of
54		encode a device a la color de la clara device de la la clara de la color de la color de la color de la color de

excessive daytime sleepiness, including structured sleep history, sleep logs and sleep questionnaires. The multiple sleep latency test, for example, is often used as an objective measurement to evaluate sleep propensity. However, in view of the large overlap between healthy subjects and subjects with sleep disorders, its use to assess sleepiness is questionable. Furthermore, its results are often jeopardised by motivational influences and the last nap effect.[37] Consequently, a feasible and convenient method that is less dependent on motivation - such as the pupillometry used in this study - seems to constitute an enrichment in field studies.[21]

Implications for clinicians and policy makers

Fatigue in the maritime setting could be counteracted by strict compliance with and monitoring of the obligatory rest and sleep times. According to Allen, Wadsworth et al. (2007)[37], it is not uncommon in seafaring for legal obligations to be neglected, for example by ignoring the minimum safety levels for crewing on board. To reduce the seafarers' workload on board during the vessel's stay in port, some job duties could be transferred to land-based workers ashore.

 In light of the frequently observed sleepiness on duty within the study sample, training should be offered for shipboard crews to improve sleep hygiene and techniques to support shortterm relaxation, such as power napping. This training should be accompanied by the strengthening of the seafarers' individual resources (e.g. training to cope with stress for health promotion) to enable them to compensate for the inevitable psychophysical strain on board. Considering the present results, limiting the work periods of seafarers (perhaps to a maximum of five months) might be an essential preventive measure in a maritime setting. Acknowledgements The authors would like to thank the seafarers and the shipping companies for taking part in this study. Many thanks are also owed to J. Hedtmann, C. Felten and B. Neubauer from the BG Verkehr for their support and the funding. Contributors MO and HJJ gave substantial contributions to the conception or design of the work or the acquisition, analysis or interpretation of data. They were equally involved in drafting the work or revising it critically for important intellectual content. Both authors gave their final approval of the version to be published. Funding This study was funded by the Berufsgenossenschaft für Transport und Verkehrswirtschaft ("BG Verkehr"), Hamburg. The funder has no involvement in the study design, the collection, analysis and interpretation of data, the writing of the report and the decision to submit the paper for publication. **Conflict of interest** Both authors declare no conflicts of interest. Patient consent Not required.

2 3	490	Eth	nics approval			
4 5	491	The study was approved by the Ethics Committee of the Hamburg Medical Association (no.				
6 7	492	PV4395).				
8						
9 10	493					
11 12	494	Data sharing statement				
13 14	495	No additional data are available.				
15	496					
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	Item No	Recommendation	Pag No
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used term in the title or the abstract	1
		(<i>b</i>) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5,7
Participants	6	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants	5,6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7,8
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	7,8
measurement		assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	
		(<i>d</i>) If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	
Results			
Participants	13*	 (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed 	9
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted	10-
		estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12

		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias	15
		or imprecision. Discuss both direction and magnitude of any potential bias	16
Interpretation	20	Give a cautious overall interpretation of results considering objectives,	15
		limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Sleepiness of day workers and watchkeepers on board at high seas: a cross-sectional study

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17 ABSTRACT

18 Objectives

To estimate the prevalence of sleepiness on duty among day workers and watchkeepers onboard.

21 Design

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22 Cross-sectional survey in a maritime field study.

23 Setting

24 10 shipping companies with container vessels under German management.

25 Participants

The whole crew (75 day workers and 123 watchkeepers) during 18 voyages on 18 different container ships.

28 Outcome measures

⁷ 29 Sleepiness on duty and efficiency of sleep using pupillometry (in a cross-shift design) and the
 ⁸ 30 SenseWear® armband activity monitor.

31 Results

The watchkeepers showed significantly shorter sleep periods than day workers (5.5 h vs. 5.8 h). The average efficiency of sleep was 69.6% and significantly lower among watchkeepers (OR 0.48; 95% CI 0.26-0.88). 396 pupillometric examinations were carried out and revealed 88 study members (22.2%) with a pupillary unrest index (rPUI) in a range characterised as "unfit for duty" and 110 seafarers (27.8%) categorised as "particular attention required". The average rPUI was similar between day workers and watchkeepers. The Epworth Sleepiness Scale revealed recent daytime sleepiness in 70 seafarers, which

- 39 was similarly often stated by day workers and watchkeepers. Based on the Stanford
- 40 Sleepiness Scale (SSS), a measurable cross-shift increase in the SSS value during the
- $\frac{1}{8}$ 41 examined shift was observed, especially among watchkeepers. The amount of time already
- ¹⁹ 42 spent on the vessel at the time of the present examination was significantly associated with
 - 43 the rPUI (p= 0.009).

44 Conclusion

45 Sleep periods of both the day workers and the watchkeepers aboard vessels were alarmingly

- 46 short and sleep efficiency was low. Sleepiness on duty is similarly prevalent among day
- ³ 47 workers and watchkeepers and seems to depend partly on the cumulative working period on
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3	48	the vessels. Preventive measures need to be taken by the shipping industry to counteract
4 5	49	fatigue (e.g.by enabling sufficient rest and sleep times).
6 7	50	
8 9	51	Key words: occupational medicine, sleepiness, seafaring, pupillometry
10 11	52	
12 13		Strongthe and limitations of this study
14	53	Strengths and limitations of this study
15 16	54	The present maritime field study shows for the first time the prevalence of seafarers'
17	55	sleepiness on duty during the sea passage, drawing a distinction between crew members
18 19	56	with and without watchkeeping duties.
20	57	The present study analysed seafarers' sleepiness on duty by applying both subjective and
21 22	58	objective methods that are less dependent on the participants' motivation (pupillometry,
22	59	armband activity monitor).
24 25	60	The study was carried out in a cross-sectional design that does not allow evaluation of
26	61	long-time effects of sleepiness.
27 28 29 30	62	> Due to the various occupational groups on board, the crews are very heterogeneous; that
	63	makes the interpretation and comparison of sleeping behaviours difficult.
31	64	
32 33 34	65	INTRODUCTION
35 36	66	Long and irregular working hours each day, combined with sleep deficiency and long periods
37 38 39 40 41	67	of work at sea, are crucial risk factors for increased sleepiness on duty among seafarers.[1,2]
	68	Strong weather conditions can also affect seafarers' performance, increase the risk of error
	69	and, consequently, cause injuries or fatalities to personnel. Psychological strain in maritime
42	70	professions can also lead to psychosomatic diseases including burnout syndrome or
43 44	71	exhaustion.[3] Some studies have stated that shipping crews suffer from psychophysical
45 46	72	exhaustion/strain due to stress and decreased periods and quality of sleep.[4] Thus, seafaring
46 47	73	still ought to be considered a high-risk profession for psychophysical exhaustion.[5,6]
48 49		
50	74	Three voyage episodes can be distinguished on board: stays in port, river passages and sea
51 52	75	passages. During the first two voyage episodes, the seafarers are often exposed to high
53	76	psychophysical stressors caused by unforeseeable and external demands that possibly need to
54 55	77	be addressed at chronobiologically adverse times (e.g. embarkation and disembarkation,
55 56	78	loading and unloading, exchange of information with port authorities). During the sea passage,
57 58	79	the engine room personnel, the electricians and the galley staff can often adhere to a regular
59 60	80	working day of 8 hours (day workers). This is better suited to chronobiologically adapted sleep 3

periods and can thus partially compensate for a potential sleep deficiency.[7] In contrast, due to obligatory navigation manoeuvres, nautical officers and a large number of the deck ratings are often required to work in a 24-hour shift system during sea passages (watchkeepers).

Nowadays, merchant ships operating internationally generally run on a 4/8-hour watch shift system. That means that three nautical officers alternate in a system which includes four hours on duty and eight hours off for each of them. Van Leeuwen, Kircher et al. (2013)[8] measured the effect of a 4/8-hour watch shift system on the alertness of seafarers in a ship simulator. They observed that especially additional overtime was associated with a subjective and objective increase in sleepiness. The authors also showed sleepiness increasing with time on watch and peaking at the end of a watch.

It has been described that watchkeeping, critical assignments during night time and irregular working periods can lead to disruptions of the crews' circadian rhythm as a precondition for sleepiness on board.[9] Dohrmann and Leppin (2017)[7] performed a systematic analysis and quality assessment of seafarers' fatigue. They observed that working nights was most fatiguing and that fatigue levels were higher toward the end of a watch or shift. According to the review, particularly the psychosocial work environment (including day workers besides the watchkeepers) had received little attention. However, the monotonous noise of the vessel's engine, the smooth ship's vibrations and the continuous slow ship's movements (during calm weather conditions) can lead to sleepiness of the whole crew on board. Higher levels of exposure to noise and vibrations can also increase sleep troubles/problems and poorer sleep guality when impacting on employees throughout the day.[10]

Working in a maritime setting is characterised by a wide variety of occupations with numerous fatiguing physical and mental strains, depending on the type of job.[11] The available maritime fatigue studies have only focused on watch officers as crew members who typically also work during night hours.[2,8,12,13] Thus, there is a lack of knowledge about sleepiness on the high seas among the other shipboard occupational groups, including the day workers. Knowing who is affected by severe sleepiness on board is of great importance to facilitate its prevention.

The present maritime field study analysed for the first time the prevalence of seafarers' sleepiness on duty during the sea passage, with a distinction between day workers and watchkeepers on board.

112 METHODS

113 Study sample

A medically trained scientist accompanied 18 sea voyages on 18 different container ships operating in the Baltic Sea and examined the crew members on board. 206 out of 225 seafarers took part in the study (response rate 91.6%). Only the results of those 198 seafarers were included who could be interviewed and examined (pupillometry) in a cross-shift design (both before the beginning and after the end of their shift). Taking part in this study was voluntary and the individual data was pseudonymised. No patients were involved in this study. All participants gave their written informed consent before taking part in this study. The study was approved by the Ethics Committee of the Hamburg Medical Association (no PV4395).

The 198 seafarers were classified into two occupational groups (75 day workers and 123 watchkeepers) (Tab. 1). The median age of the exclusively male study sample was 36.7 years (19 - 67 years) and significantly higher among the day workers. Furthermore, the day workers had a somewhat higher body weight than the watchkeepers. No differences were observed in the circadian preference when comparing watchkeepers with day workers. The difference between the two occupational groups in terms of their marital status and the presence of children was not noteworthy. 49.0% of the seafarers either smoked or were former smokers.

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³⁸ ³⁹ 132 Patient and Public Involvement

The present study focused on the sleepiness of shipboard crews; patients and/or public were not the target group of this study. Previous studies revealed that sleepiness constitutes one of the major problems amongst seafarers. All German shipping companies owning container ships were invited to participate in this study. 10 shipping companies agreed and put 18 different container ships at our disposal (1 ship of companies A, B, C, and D, 2 ships of companies E, F, G, and H, and 3 ships of companies I and J participated).

All seafarers on board of these vessels were informed about our study design, aim and
 All seafarers on board of these vessels were informed about our study design, aim and
 content and were encouraged to participate (participation rate 88.0%). After completion of
 our board examination, an individual medical report was created and sent to each of the
 accepting seafarers to their home address.

2 3			Devenerkere	Matabkaanava		
4			Day workers	Watchkeepers		
5			(54 engine room personnel,	(46 nautical officers, 77		
6 7 8			16 electricians, 5 galley staff)	deck ratings)		
9 10		Number; n (%)	75 (37.9%)	123 (62.1%)		
11 12 13 14		Age ; median years (min- max)	44 (19-67)	35 (19-63)		
15 16 17		BMI; median (min-max)	26 (19-40)	24 (17-36)		
18 19 20		Morning-Evening-Question	nnaire, n (%)			
21 22		Morning type	45 (60.0%)	68 (55.2%)		
23 24 25		Intermediate type	24 (32.0%)	46 (37.4%)		
26 27		Evening type	6 (8.0%)	9 (7.4%)		
28 29 30		Origin ; n (%)				
31 32		European	38 (50.7%)	47 (38.2%)		
33 34 35		Southeast Asian	37 (49.3%)	76 (61.8%)		
36 37		Married; n (%)	53 (70.7%)	87 (70.7%)		
38 39		Children; n (%)	53 (70.7%)	82 (66.7%)		
40 41 42		Smoking status; n (%)				
43 44		Never smoked	36 (48.0%)	65 (52.8%)		
45 46 47		Former smoker/smoker	39 (52.0%)	58 (47.2%)		
48 49	144	Tab. 1 Demographic and life	estyle parameters by occupationa	l groups on board		
50 51	145					
52 53	146	To assess long-term effects	on sleep during their current peri	od on board, the participants		
54 55	147	147 were additionally grouped in respect of their stay on board at the time of examina				
55 56 57	148	months, 2-5 months and > 5	i months).			
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50 **Examination procedure**

All seafarers taking part in the study were examined with the SenseWear® armband monitor and pupillometry both during shifts and during time off (including sleep time). These devices were selected because they did not considerably disturb the crew's daily routines (low weight, no cable connection, easy use), which was a precondition. The present study monitored the sleep of all seafarers in a continuous mode during a period of at least 72 hours of observation. An observation time of at least 3 days during the sea passage was chosen because of the known variations of sleep quality on a daily basis.

The average period of wearing the armband monitor was 66.3 h (SD 14.8 h) (>92% of
observation time) and did not differ between the occupational groups. The pupillometric
examination took place within this observation period.

162 Efficiency of sleep

The SenseWear® armband activity monitor is a device that weighs 82 g and is worn on the right upper arm just above the triceps muscle according to its validation requirements. While wearing the armband monitor, the seafarers could easily operate the device for themselves without support from the shipboard examiner. The monitor is designed to analyse the profile of physical activity (movement, lying down or sleeping). The collected information allows the estimation of sleep efficiency by establishing the ratio of the duration of sleep and the time spent lying down. Thus, efficiency of sleep expresses the time spent actually sleeping while lying down.

171 The armband monitor has already been successfully applied in many studies as a detector of
 172 sleep.[14-19] Current studies reveal that the total sleep time and time in bed correlate
 173 significantly between the measurements of the armband monitor and the polysomnography
 174 (p<0.001); the armband has proved to be superior in comparison to other commercially
 175 available activity monitors.[16]

177 **Pupillometry**

178 The device *Fit-For-Duty* by AmTech was used to conduct pupillometric examinations [20].

- ¹⁶ 179 The Pupillographic Sleepiness Test is considered an objective method for documenting
 - 180 sleepiness by monitoring spontaneous and unconscious oscillations of the pupil without

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stimulating light. The result is a pupillogram, which can be used to deduct the pupillary unrest index (rPUI). This parameter therefore is an objective measure for the variance of the diameter of the pupil. A recent study suggested the Pupillographic Sleepiness Test as a reliable measurement for detecting drowsiness-related impairment.[21]

The rPUI is compared to standard values. Results < 1.02 are considered normal. "Particular attention required" is the characterisation of results \geq 1.02 and < 1.53. An index \geq 1.53 is rated as "unfit for duty". This methodology has repeatedly been used in scientific studies to assess sleepiness.[22-24]

During a sea passage, the pupillometric examination was performed twice according to a cross-shift design for all 198 seafarers included in the study sample. The chosen sea passages lasted for at least 24 hours and therefore allowed a regular operation of the vessel and predictable working procedures. The pupillometric cross-shift examination took place 15 minutes before the respective shift started and directly after it ended so that that shift was neither shortened nor disturbed by this examination. In general, it is not likely that the seafarers were distinctly disturbed by the examination with the chosen devices or by the presence of the medical staff on board.

The engine room personnel, the electricians and the galley staff (without watchkeeping duties) were examined during an average work shift that lasted 8 hours (most likely from 8:00 h to 17:00 h including a lunch break of 1 hour). As watchkeepers have two work units per day -each of them about 4 h (six shift periods: 0-4 h, 4-8 h, 8-12 h, 12-16 h, 16-20 h and 20-24 h) - a split sleeping time is often observed in this occupational group. The watchkeepers were examined during a randomly selected shift period with the aim of achieving an equal representation of these periods (about 20 watchkeepers/shift period). For the assessment of cross-shift reactions, it was unavoidable to compare the PUI and SSS between two occupational groups with different lengths of working times.

Questionnaire

In the framework of a standardised interview, all seafarers were asked about their demographic data, their subjective physical and mental stress level, their sleep period before the examined shift and their current working time. Additionally, daytime sleepiness was estimated by using the Epworth Sleepiness Scale. [25]. This is a self-administered questionnaire which is shown to provide a measurement of the subject's general level of daytime sleepiness. Retrospectively, the probability of nodding off or falling asleep in eight

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typical everyday situations is investigated. Furthermore, the Stanford Sleepiness Scale was 214 used as a self-rating scale to quantify progressive stages of sleepiness.[26] Individual 215 circadian fluctuations in sleepiness and alertness can be determined through repetition in 216 217 intervals. In the present study, this scale assessed the sleepiness before and after a shift. 218 Finally, the seafarers filled in the Morning-Evening-Questionnaire (rMEQ) for the assessment 219 of the circadian preference.[27, 28] This questionnaire evaluates against individual differences in the circadian rhythm. Responses to the questions are combined to form a composite score 220 221 that indicates the degree to which the respondent favours morning versus evening.

Statistics 223

Statistic analysis was performed with SPSS (version 24, IBM Corporation). The Shapiro-Wilk 224 225 test was used to test for normal distribution of data. Where variables were not normally distributed, non-parametric tests (Mann Whitney-U test, Wilcoxon test) were used, otherwise 226 227 the T-test was applied in the case of normal distribution. The Chi-squared test was used to 228 analyse differences in frequencies of parameters. Crude odds ratio (OR) including 95% confidence intervals was calculated by binary logistic regression. For adjustment reasons, 229 age, rank (officer vs. rating), the examination time of day and duration of stay on board at the 230 time of examination were added. Furthermore, correlations were analysed by using the 231 232 Spearman test.

All indicated p-values were two-sided, and a p-value of < 0.05 was regarded as statistically 233 significant. 234

RESULTS 236

The number of months day workers had already spent on the vessel at the time of examination 237 238 and during their current contract was similar to that of watchkeepers. In particular, the 239 stratification of the seafarers in tertiles concerning their recent stay on board did not reveal any 240 differences (Tab. 2).

241 The Epworth Sleepiness Scale (ESS) showed that 70 seafarers (35.4%) had recently been suffering from daytime sleepiness. The ESS value increased significantly (p= 0.004) with the 242 243 length of stay on board. No differences were observed when differentiating according to the 244 obligation to perform watchkeeping duties (p= 0.113). Younger seafarers below the age median of 37 years indicated daytime sleepiness more often than older colleagues (p= 0.014). 245

		Occu	pational groups					
		Day workers	Watchkeepers	р				
		(n=75)	(n=123)	-				
0	Stay on board							
1 2 3	At the time of examination; median months (min-max)	3 (1-12)	3 (0-11)	0.837*				
4 5 6 7	Frequency according to tertile; n (%)							
, 8 9 0	≤ 2 months	28 (37.3%)	45 (36.6%)					
1	> 2 and ≤ 5 months	28 (37.3%)	45 (36.3%)	0.973#				
2 3	> 5 months	19 (25.3%)	33 (26.8%)					
4 5	Scheduled (min-max)	7 (2-13)	8 (1-12)	0.719*				
6 7 8	Epworth Sleepiness Scale (ESS)	, median (min-max)						
9 0	Score value (SD) ¹	8 (0-15)	8 (0-21)	0.113*				
1	≥ Cut off value (10), n (%)	26 (34.7%)	44 (35.8%)	0.875#				
2 3 246	*Mann Whitney-U test #Chi-squared test ¹ sleepiness scale from 0 ("no chance to doze in")							
4 5 247	up to 24 ("maximum chance to doze in")							
6 7 248	Tab. 2 Stay on board and subjectiv	e assessment for daytime	sleepiness					
8 9 249								
0 1 250	Cross-shift examinations							
3 4 251	To analyse the recent alertness att	ributed to a representative	shift, 198 seafarers were a	sked				
5 252 6	to participate in a cross-shift exami	nation. According to the re	sults of the armband monit	or,				
7 253	the cumulative sleep time before the examined shift (including split sleep episodes) lasted for							
8 9 254	5.6 hours (SD 1.0) per 24 h period, while watchkeepers had significantly shorter sleep							
) 255	durations compared to the day workers (Tab. 3). The working hours during the examined							
l <u>2</u> 256	shift were significantly lower amongst watchkeepers. Concerning their subjective stress level							
³ 257	during the shift examined, significantly more watchkeepers experienced mental demands							
+ 5 258	than day workers (OR 2.35; 95% CI 1.24-4.44). After adjustment for age, ranking,							
6 7 259	examination time of day and recent number of months at the time of investigation, this							
8 260	elevated risk for mental stress remained significant among watchkeepers.							
9 0		10						

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2		
3	261	During the examined shift, the average sleep efficiency was 69.3% and was significantly
4 5	262	lower among watchkeeping seafarers than day workers (OR 0.48; 95% CI 0.26-0.88). This
6 7	263	finding was independent of the age, ranking, time of day of the examination and the recent
8	264	duration of shipboard stay. 63.7% of the participating seafarers stated that they had
9 10	265	consumed coffee within the past 4 hour before our pupillometric examination on board
10 11 12	266	irrespective of their occupational group.
13 14	267	Before their shift, the mean value on the Stanford Sleepiness Scale (SSS) was 2.6 (SD 1.4)
15	268	(2= "functioning at high levels, but not fully alert"; 3= "awake, but relaxed; responsive but not

Iy alert"; 3= "awake, but relaxed; responsi ot is, but not ful fully alert"); after the work shift, the level of sleepiness was significantly higher (3.2 (SD 1.8)) (Wilcoxon test: p = 0.001) indicating a measurable increase in the subjective sleepiness in the course of a shift. This was especially true for watchkeepers although the length of their working time was much shorter than that of day workers (Tab. 3). Consequently, more watchkeepers reported current sleepiness than day workers after the examined shift.

A remarkable number of 35 seafarers (17.7%) reported a level of sleepiness on duty of 6/7 on the SSS (6= "sleepy, woozy, fighting sleep, prefer to lie down"; 7= "no longer fighting sleep; sleep onset soon; having dream-like thoughts") after their shift. According to SSS, more young seafarers considered themselves to be tired (cross-shift SSS of all crew members below and above the median age of 37 years: 3.1 vs. 2.6; p= 0.011). Focusing on the group of watchkeeping seafarers, those who were on duty between 00:00-04:00 h and 04:00-08:00 h more often displayed severe sleepiness on duty after their shift (SSS≥ 5) (72.2% and 50.0% respectively).

The 396 pupillometric examinations (15 minutes before and after a shift) revealed that the change in rPUI values during the cross-shift observation did not reach a significant level in intra-individual comparison (mean rPUI before vs. after the working shift: 1.14 vs. 1.19; cross-shift rPUI change: p= 0.355). After stratification, the intra-individual cross-shift change in rPUI values was also not dependent on the occupational groups (Tab. 3), while the different length of working time has to be taken into account.

The objective sleepiness on duty in the study sample was not dependent on age (only a slight tendency for younger seafarers after shift; p= 0.064). During the examination, 12 seafarers fell asleep and therefore were assigned to the group "unfit for duty". The pupillary unrest index in 88 examinations showed the seafarers were "unfit for duty"; additionally "particular attention required" was classified in 110 cases (27.8%). Therefore, only half of the examinations were "normal". No differences were observed in the pupillary unrest index between seafarers with and without watchkeeping duties.

1 2

60

2											
3	295	In concordance to the	eir subjective self-rep	ort in SSS, watchkee	epers displayed som	ewhat					
4 5	296	higher rPUI values af	ter the shift than day	workers (Tab. 3). Th	e analysis of the co	rrelation of					
6	297	the subjective assess	-		-						
7		pupillometry only revo	•	• • •	-						
8 9	298										
10 11	299 Within the group of watchkeepers, stronger sleepiness on duty (rPUI \ge 1.2) after a shift										
12	300	lasting from 00:00-04	:00 h and from 04:00)-08:00 h was observ	red (75.0% and 55.6	%					
13 14	301	respectively).									
15											
16 17	302										
17 18											
19			Occupation	nal groups							
20 21			Day workers	Watchkeepers	Crude OR*	Adjusted OR#					
22			(n=75)	(n=123)	(95% CI)	(95% CI)					
23 24			(11 7 0)	(11 120)							
24	Tin	ne periods in the cont	ext of the current p	oupillometric examination	nation, mean hours	(SD)					
26		Sleep period before ¹	5.8 (1.1)	5.5 (1.0)	0.85 (0.78-0.92)	0.88 (0.80-0.95)					
27 28			0.0 (11)								
29	,	Working hours				0.57 (0.46-0.92)					
30 21		examined	9.5 (1.5) 4.9 (1.6)		0.56 (0.43-0.88)	0.57 (0.40-0.92)					
31 32											
33	Su	ubjective stress level during examined shift, n (SD)									
34 35		Physical ²	48 (64.0%)	78 (63.4%)	0.96 (0.52-1.79)	0.51 (0.24-1.08)					
36		Filysical	40 (04.070)	78 (03.478)	0.90 (0.32-1.79)						
37		Mental ³	41 (54.7%)	94 (76.4%)	2.35 (1.24-4.44)	2.18 (1.08-4.40)					
38 39											
40	Sle	ep efficiency ¹									
41 42		(0()	70 70/ (44 00/)	07.00/ (40.00/)		0 40 (0 05 0 04)					
43	- IV	ean (%)	72.7% (11.8%)	67.9% (12.2%)	0.48 (0.26-0.88)	0.48 (0.25-0.91)					
44	Sta	Inford Sleepiness Sca	ale (SSS) ⁴ , mean (SI))							
45 46	0			24(47)	0 72 (0 40 4 40)	0.04 (0.55.4.20)					
47	Cri	oss-shift⁵	2.6 (1.4)	3.1 (1.7)	0.73 (0.48-1.10)	0.84 (0.55-1.29)					
48 49	Tin	ne depending									
49 50		с и I:0	2.5 (1.4)	2.6 (1.5)	1.07 (0.59-1.95)	0.91 (0.49-7.70)					
51	- B	efore the shift									
52 53	- A	fter the shift	2.8 (1.4)	3.5 (1.9)	1.81 (1.01-3.25)	1.25 (0.66-2.37)					
54	~										
55 56	Pu	pillary unrest index (r	rui), mean (SD)								
56 57	Cre	oss-shift⁵	1.14 (0.66)	1.18 (0.65)	0.92 (0.61-1.40)	1.05 (0.70-1.61)					
58			· · ·	. ,		. ,					
59 60											

1 2 3	T :								
4 5		ne depending efore the shift	1.14 (0.67)	1.12 (0.62)	0.96 (0.52-1.74)	0.86 (0.46-1.61)			
6 7									
8		fter the shift	1.13 (0.66)	1.23 (0.65)	1.55 (0.85-2.84)	1.31 (0.70-2.46)			
9 10	Lev	vel (n=396) of sleepines	s on duty⁵ n (%)						
11 12 13	- N	one ⁶	78 (52.0%)	120 (48.8%)					
13 14	- Pa	articular attention	39 (26.0%)	71 (28.9%)	0.789				
15 16	re	equired ⁷	39 (20.0 %)	71 (20.976)	0.769				
17 18	- U	nfit for duty ⁸	33 (22.0%)	55 (22.3%)					
19	303	*the crude OR bases or	n the median of para	meters and includ	es differences betwee	en occupational			
20 21	304	groups and the examin	ation time of day #a	idjusted for age, ra	ank (officer vs. rating)	and duration of			
22 23	305	stay on board at the tim	ne of examination						
24	306	¹ according to measurer	ments with the armb	and monitor, relate	ed to an average 24 h	iour period			
25 26	307	² "have you experienced	d physical stress dur	ing the examined	shift?" ³"have you ex	perienced			
27 28	308	mental stress during the	e examined shift?"						
29 30	309	⁴ SSS-scale from 1 ("fee	el active and vital") u	p to 7 ("almost dre	aming/falling asleep")			
31 32 33 34 35 36	310	⁵ all values exploited (before and after the shift) ⁶ rPUI< 1.02 ⁷ rPUI≥ 1.02 and < 1.53 ⁸ rPUI≥ 1.53							
	311	Tab. 3 Cross-shift examination concerning sleep characteristics							
	312								
37 38	313	Regardless of the occu	pational groups, the	objective sleepine	ess on duty (rPUI) did	not			
39 40	314	correlate to the cumula	tive sleep over a 24-	h period before th	e examined shift, the	sleep			
41	315	efficiency and the object	ctive assessment of	the ship's motion a	according to the ship's	s journal			
42 43	316	parameters. An associa	ation was observed,	however, betweer	the duration of time	already			
44 45	317	spent on board at the ti							
46	318	stratification according		•					
47 48	319	especially true for those		0 ,	, i	2			
49 50	320	of less than 2 months, 2				0			
51	321	1.32). The bivariate gro		C	5	an 5			
52 53	322	months showed signific	ant pre-shift differen	ices in rPUI (1.08	vs. 1.32; p= 0.002).				
54 55	323								
56 57									
58 59									
60				13					

324 DISCUSSION

Being a seafarer requires strong mental stability and a robust physical constitution, along with an adaptive and flexible attitude. However, stress and fatigue can hinder maritime professionals in performing effectively.[29] Seafarers spend both their working and leisure time over a couple of months in the restricted shipboard environment that can impact sleep quality and lead to sleepiness.[5] In the present study, a significantly lower sleep efficiency averaging at 69.3% and a higher subjective sleepiness assessment (SSS) after the shift were found among watchkeepers compared to day workers. In addition, the examinations carried out on board objectified critically short durations of the seafarers' sleep average (5.6 h per 24 h) particularly among watchkeepers.

Especially the short sleeping times correspond very well with the results of international studies.[30] Sleep periods on board are often interrupted (potentially due to ship's movements or sudden noise evoked by the handling of containers in harbours).[31] These effects can explain why many seafarers, including day workers, suffer from sleepiness on the high seas. The sleep interruptions are particularly often an inevitable consequence of the watch shift requirements with two 4-h working shifts per day. Thus, on any watch system it is common that seafarers have several sleep episodes per 24-h period. Daytime sleep is usually much less efficient than sleep obtained at the circadian nadir. It can be assumed that some watchkeepers have problems falling asleep after a stressful working day (with scarcely any opportunities for sleep); this results in decreased sleep efficiency. Split sleep among watchkeepers can also not be excluded as the cause of this low sleep efficiency.

Although this study has not proved that sleepiness on duty depends directly on disturbances of the sea during passages, we measured generally low sleep efficiency. This means that not only the amount, but also the quality of sleep is insufficient among the examined seafarers on board. Frequent sleep disruptions can impair alertness to a great degree and consequently lead to an increased risk of accident on board.[32]

Despite similar physical stress levels, the crew members with watchkeeping duties experienced mental stress subjectively more frequently than day workers. This was probably due to their reduced and interrupted sleep time as well as their high job responsibility, which represents a distinct mental stressor. Correspondingly, the watchkeepers starting with a subjective sleepiness level similar to that of the day workers had a significantly more pronounced increase in their sleepiness level after the cross-shift examination. Although no significance level was reached, the cross-shift pupillometry of watchkeepers also indicated a higher level of objective sleepiness after the shift than that of day workers. In this context, the

3	358	difference in the length of examined working time between day workers and watchkeepers
4 5	359	has to be highlighted. The watchkeepers' higher value for SSS and, by trend, for PUI after
6 7	360	the examined shift is remarkable as they had worked a considerably shorter time than the
, 8 9	361	day workers. Thus, these differences are surely underestimated in this study.
10	362	According to Wilhelm (2008)[33], severe sleepiness is displayed by drivers who did not sleep
11 12	363	during the chronobiologically relevant time frame (0:00 h - 05:00 h). In the maritime setting,
13 14	364	this especially applies to watchkeepers. These crew members, who are on duty during the
14 15	365	inconvenient time frames between 0:00-04:00 h and 04:00-08:00 h, reported the expected
16 17	366	subjective severe sleepiness, which was also objectively measured using pupillometry. In
18	367	this context, it has to be taken into account that most fatigue-induced shipping disasters take
19 20	368	place in these time frames.[34]
21 22	369	According to the results of the Morning-Evening-Questionnaire in the present study, the
23 24	370	morning type was overrepresented in the study group. Due to the fact that their work shifts
24 25	371	on board often begin early in the morning over several months in a stretch, many seafarers
26 27	372	are surely adapted to this daily rhythm and subjectively feel particularly fit in the early
28	373	morning-hours. This is a hypothesis for the skewed distribution towards the morning type in
29 30	374	our study that needs confirmation in further field studies on board.
31 32	375	Watchkeepers are habitual shift workers, often experiencing circadian misalignment due to
33	376	their irregular work/rest schedules. This might be one explanation as to why the small
34 35	377	number of available maritime field studies about seafarers' fatigue has exclusively focused
36 27	378	on watchkeepers. Importantly, this study demonstrates that day workers also often
37 38	379	experience severe sleepiness; more than 20% of both the watchkeepers and the day
39 40	380	workers were characterised as "unfit for duty" during their regular shift and only every second
41	381	pupillary measurement was regarded normal. The fact that 12 seafarers had fallen asleep
42 43	382	during the 11-min pupillary examination and that 35 crew members regarded themselves as
44 45	383	very sleepy post-shift (SSS \geq 6) confirms these alarming pupillometric results. In light of the
45 46	384	strong impact on the ships' safety, further studies are urgently needed to examine and
47 48	385	counteract the sleepiness of both the shipboard watchkeepers and the day workers.
49 50	386	Furthermore, this study observed that the duration already spent on the vessel at the time of
51	387	the examination correlated with the PUI. This finding could indicate a cumulative effect on the
52 53	388	seafarers' sleepiness. Officers normally have far shorter periods on board than ratings
54	389	(averaging 2.5 vs. 4.1 months in a row). Daily sleepiness as a consequence of high work
55 56	390	strain lasting for many months seems to be plausible. According to the present results,
57 58	391	working periods below five months in a row seem to be reasonable for seafarers. Further
59 60		15

392 studies are required to evaluate this hypothesis and to determine recommendations for393 maximum working periods on board.

Subjective assessments of sleepiness only displayed a weak correlation with the objective pupillometric results. This could lead to a misjudgement of the seafarers' current psychophysical performance, which might also have safety implications. Younger and less experienced crew members reported more severe sleepiness on duty but did not display differences in their pupillometric measurements. In view of the frequently described high prevalence of fatigue-related accidents in seafaring, a high level of psychophysical stress, but also a misjudgement of their alertness is assumed. Thus, it is recommended to use complementary objective methods besides questionnaires in studies to determine the level of fatigue among examined employees. Future studies should also explore possibilities and evaluate acceptance by the crew to develop more flexible shift scheduling that allows the consideration of circadian preferences and, possibly, individual preferences of the watchkeeping seafarers.

26 406

407 Limitations

The present study has some limitations that need to be addressed. Firstly, the sample size of this study is rather small, but in comparison to other available maritime studies the examined seafarer population is far larger. Secondly, the study was carried out in a cross-sectional design that does not allow the evaluation of long-time effects of sleepiness. Due to the permanently changing shipping crews on the vessels, it is hardly possible to arrange long-time follow-up examinations of a noteworthy proportion of seafarers. Thirdly, due to the various occupational groups on board, the crews are very heterogeneous and that makes the interpretation and comparison of sleeping behaviours difficult, also when considering the large inter-individual and intra-individual variability in sleep. Fourthly, the present study design does not provide information about the seafarers' sleep architecture. Sleep loss is generally compensated by changing the sleep architecture towards more so-called slow-wave sleep.

The armband monitor used is mainly suitable for measuring bed rest[35] and has only a limited informative value about sleep architecture, which is normally measured in sleep laboratories ashore, e.g. using polysomnographic techniques.[36] In maritime field studies, however, the use of such extensive examinations (only one measurement per night) does not appear to be very suitable on board. Furthermore, the determination of lying time with this monitor may be somewhat imprecise so that an underestimation of the sleep efficiency cannot be excluded. Although the sleep diaries frequently used for sleep assessment are only subjective procedures,

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3	426	in further studies the armband monitor examination should be accompanied by the use of sleep
4 5	427	diaries as they allow checking the start and end times of sleep.
6 7	428	Moreover, pupillometry has yet not been established as a reliable screening test for sleepiness
8	429	[36]. Particularly sleep latency or sleep architecture are the domains of extensive examinations
9 10	430	in sleep laboratories ashore and were not the focus of the present maritime field study.
11	431	Additionally, the PUI correlated with the seafarers' subjective statements. Further studies are
12 13	432	recommended to evaluate the validity of these devices for their use in maritime field settings as
14 15	433	well as to check their suitability on board and their acceptance by the seafarers on the high seas.
16 17	434	Despite these limitations, the present study analyses for the first time the prevalence of
18	435	sleepiness in seafarers with and without watchkeeping duties; the findings require further
19 20	436	confirmation in a larger cohort. Furthermore, the present maritime field study analysed the
21 22	437	prevalence of seafarers' sleepiness on duty by applying various subjective and objective
23	438	methods. Up to now, most maritime studies about seafarers' sleepiness have not been carried
24 25	439	out on board vessels and only rely on subjective methods.[37] Questionnaires are, however,
26	440	subjective instruments, consequently depending on self-reported data, so that underreporting
27 28	441	might have occurred.[38] Additionally, these subjective instruments do not reveal
29 30	442	biophysiological differences that might promote the understanding of sleepiness on
31 32	443	board.[21,39]
33 34	444	Nowadays, a variety of subjective and objective instruments exist for assessment of
35	445	excessive daytime sleepiness, including structured sleep history, sleep logs and sleep

questionnaires. The multiple sleep latency test, for example, is often used as an objective measurement to evaluate sleep propensity. However, in view of the large overlap between healthy subjects and subjects with sleep disorders, its use to assess sleepiness is questionable. Furthermore, its results are often jeopardised by motivational influences and the last nap effect.[37] Consequently, a feasible and convenient method that is less dependent on motivation - such as the pupillometry used in this study - seems to constitute an enrichment in field studies.[21]

Implications for clinicians and policy makers

Fatigue in the maritime setting could be counteracted by strict compliance with and monitoring of the obligatory rest and sleep times. According to Allen, Wadsworth et al. (2007)[37], it is not uncommon in seafaring for legal obligations to be neglected, for example by ignoring the minimum safety levels for crewing on board. To reduce the seafarers' workload on board during the vessel's stay in port, some job duties could be transferred to land-based workers ashore.

In light of the frequently observed sleepiness on duty within the study sample, training should be offered for shipboard crews to improve sleep hygiene and techniques to support shortterm relaxation, such as power napping. This training should be accompanied by the strengthening of the seafarers' individual resources (e.g. training to cope with stress for health promotion) to enable them to compensate for the inevitable psychophysical strain on board. Considering the present results, limiting the work periods of seafarers (perhaps to a maximum of five months) might be an essential preventive measure in a maritime setting. Acknowledgements The authors would like to thank the seafarers and the shipping companies for taking part in this study. Many thanks are also owed to J. Hedtmann, C. Felten and B. Neubauer from the BG Verkehr for their support and the funding. Contributors MO and HJJ gave substantial contributions to the conception or design of the work or the acquisition, analysis or interpretation of data. They were equally involved in drafting the work or revising it critically for important intellectual content. Both authors gave their final approval of the version to be published. Funding This study was funded by the Berufsgenossenschaft für Transport und Verkehrswirtschaft ("BG Verkehr"), Hamburg. The funder has no involvement in the study design, the collection, analysis and interpretation of data, the writing of the report and the decision to submit the paper for publication. **Conflict of interest** Both authors declare no conflicts of interest. Patient consent Not required.

2 3	491	Eth	nics approval
4 5	492		e study was approved by the Ethics Committee of the Hamburg Medical Association (no.
6			
7 8	493	PV	4395).
9 10	494		
10 11 12	495	Dat	ta sharing statement
13 14	496	No	additional data are available.
15	497		
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	Item No	Recommendation	Pag No
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of	5,7
Dantiainanta	(recruitment, exposure, follow-up, and data collection	5.6
Participants	6	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants	5,6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7,8
Data sources/	8*	For each variable of interest, give sources of data and details of methods of	7,8
measurement		assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confounding	8
		(<i>b</i>) Describe any methods used to examine subgroups and interactions	8
		(c) Explain how missing data were addressed	
		(<i>d</i>) If applicable, describe analytical methods taking account of sampling	
		strategy (e) Describe any sensitivity analyses	
		(<u>e</u>) Describe any sensitivity analyses	
Results	10*		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in	9
		the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
	1 4 4	(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	
Outcome data	15*	Report numbers of outcome events or summary measures	9
Main results	16	(<i>a</i>) Give unadjusted estimates and, if applicable, confounder-adjusted	10-
	10	estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	12

(b) Report category boundaries when continuous variables were categorized

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	(c) If relevant, consider translating estimates of relative risk into absolute	11
	risk for a meaningful time period	
17	Report other analyses done-eg analyses of subgroups and interactions, and	
	sensitivity analyses	
18	Summarise key results with reference to study objectives	13
19	Discuss limitations of the study, taking into account sources of potential bias	15-
	or imprecision. Discuss both direction and magnitude of any potential bias	16
20	Give a cautious overall interpretation of results considering objectives,	15-
	limitations, multiplicity of analyses, results from similar studies, and other	16
	relevant evidence	
21	Discuss the generalisability (external validity) of the study results	16
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22	Give the source of funding and the role of the funders for the present study	17
	and, if applicable, for the original study on which the present article is based	
	18 19 20 21	risk for a meaningful time period 17 Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses 18 Summarise key results with reference to study objectives 19 Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias 20 Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence 21 Discuss the generalisability (external validity) of the study results 22 Give the source of funding and the role of the funders for the present study

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.