

Association Between Subjective Sleep Quality and Quality of Life (QOL) Linked with Claims Data in the DeSC Database in Japan

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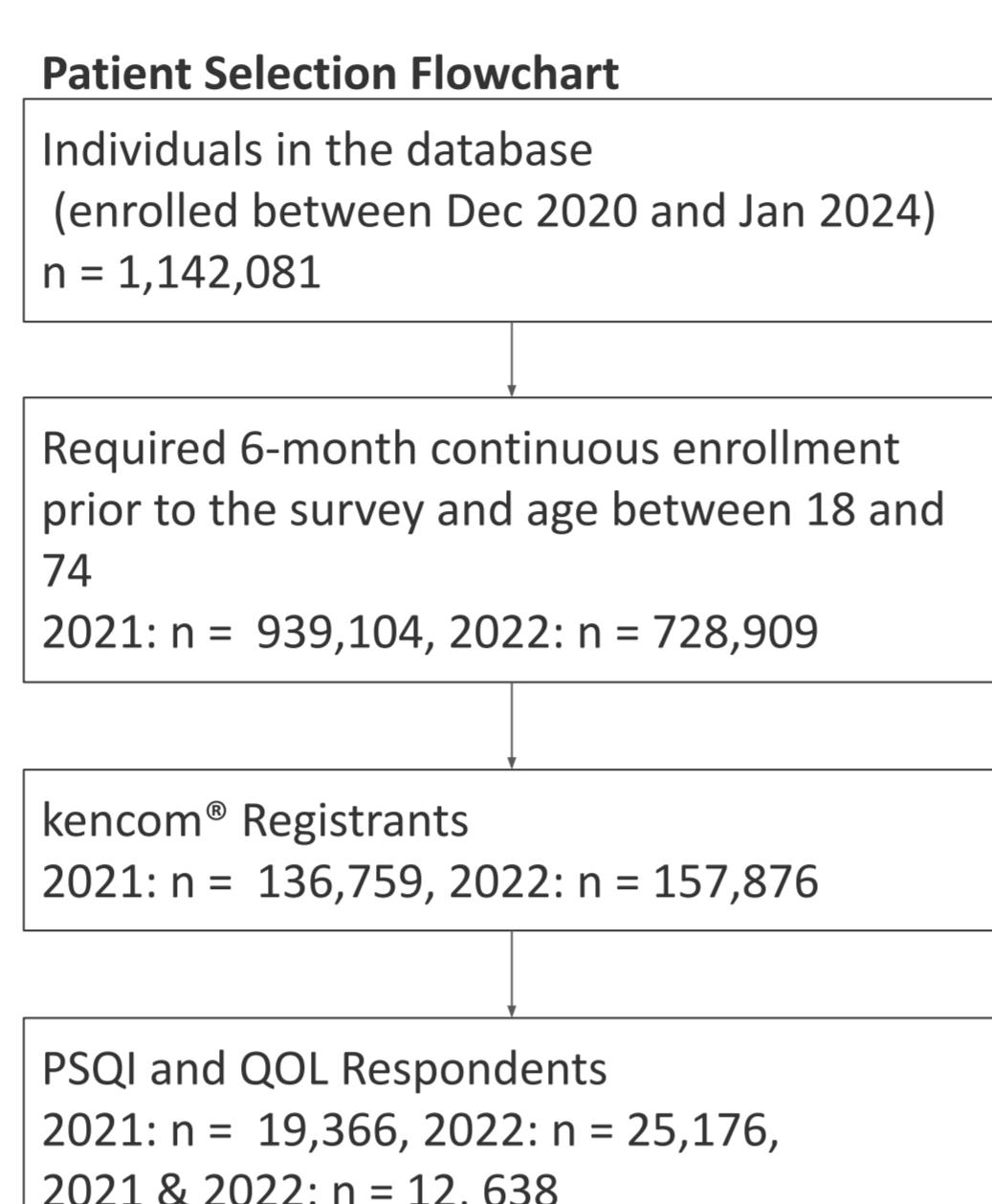
Background

- Limitations of Traditional Databases:** Conventional claims databases lack Patient-Reported Outcomes (PROs), which limits their capability to capture a comprehensive view of treatment effectiveness.
- Importance of PROs in Real-World Research:** The integration of PROs is essential in real-world research, especially in fields such as sleep disorders where Quality of Life (QOL) is a primary concern.
- Research Gap:** While the relationship between sleep quality and QOL has been suggested, there has been a lack of longitudinal investigation using large-scale, real-world clinical data.

Methods

Data Source and Study Design

- The DeSC database (DB) includes anonymized data collected from medical claims, annual health checkups, and enrollment information. In addition, data such as daily step counts are collected and surveys are distributed biannually through the smartphone application kencom® (a total of 13 times since 2019). This database enables us to link anonymized claims data with Patient-Reported Outcomes (PROs).
- Among the several health insurances available in Japan, DeSC covers Employee Health Insurance (EHI), National Health Insurance (NHI), and the Late-Stage Elderly Healthcare System (LSEHS). The PROs in the DeSC DB includes survey respondents who are covered by the EHI and NHI plans.
- The study design combined a cross-sectional analysis at two survey points (December 2021 and December 2022) with a longitudinal analysis of participants who responded to both surveys.



Measures

- Sleep Quality:** Assessed using the Japanese version of the Pittsburgh Sleep Quality Index (PSQI). The total score (0-21) was used as a continuous variable, and a PSQI score > 5 was used to define the "poor sleep quality" group.
- Health-Related QOL:** The utility score from the Japanese version of the five-level version of the EuroQol five-dimensional questionnaire (EQ-5D-5L), calculated using the Japanese value set, was used as the indicator for QOL.

Statistical Analysis

- A multiple regression analysis was used to evaluate the association between the PSQI score (independent variable) and the EQ-5D-5L score (dependent variable).
- Covariates: Age Group (categorical), Sex (categorical), Survey year (2021/2022), and the following variables were assessed for the 6 months prior to the survey:
 - Severity of comorbidities (Charlson Comorbidity Index score)
 - Medical costs (outpatient and inpatient)
 - Number of days of medical care (outpatient and inpatient)
- All statistical analyses were performed using R version 4.2.2.

Results

Overall Population	2021		2022		kencom® Registrants	PSQI Registrants		2times
	n	n	n	n		2021	2022	
n	939,104	728,909	136,759	157,876	19,366	25,176	12,638	
sex(n, %)								
Female	461,479(49.1)	349,834(49.0)	55,986(40.6)	63,164(40.0)	6,039(31.2)	8,522(33.9)	3,739(29.6)	
Male	477,930(50.9)	379,065(50.0)	81,261(59.4)	74,706(59.0)	13,327(68.8)	16,651(66.1)	8,899(70.4)	
age(mean, sd)	52.1(15.7)	50.0(15.0)	46.1(11.9)	46.1(11.4)	48.7(10.4)	49.0(10.7)	49.4(10.0)	
age_group(n, %)								
18-24	59,396(6.3)	51,917(1.1)	3,862(2.8)	4,824(3.1)	224(1.2)	240(1.0)	840(7.7)	
25-29	43,474(4.6)	39,488(4.4)	9,967(7.3)	12,537(7.7)	743(3.8)	920(3.7)	378(3.0)	
30-34	52,174(5.6)	45,036(3.2)	11,701(8.6)	13,098(8.4)	1,200(6.2)	1,402(5.6)	73(5.8)	
35-39	53,836(5.6)	54,987(5.3)	14,272(10.6)	15,871(10.1)	1,649(9.1)	1,951(8.0)	1,208(8.1)	
40-44	49,393(5.0)	47,530(5.0)	16,370(10.5)	21,931(10.5)	2,293(11.0)	2,600(10.0)	1,444(10.4)	
45-49	50,851(10.9)	50,761(10.9)	21,945(16.6)	26,395(16.8)	3,207(17.0)	3,908(15.5)	2,271(15.6)	
50-54	101,935(10.9)	85,555(11.7)	24,898(18.2)	26,202(18.7)	4,137(21.3)	5,101(20.3)	2,849(22.5)	
55-59	86,359(2.2)	76,105(1.0)	18,853(13.8)	23,298(14.8)	3,812(6.4)	4,533(8.0)	2,175(17.2)	
60-64	65,549(1.1)	64,318(1.8)	8,090(6.5)	12,047(7.7)	1,672(8.6)	2,710(10.8)	1,150(9.1)	
65-69	125,051(3.3)	75,168(0.3)	4,547(3.3)	5,583(3.5)	718(3.7)	1,173(4.7)	504(4.0)	
70-74	153,471(3.3)	98,386(1.5)	277(1.4)	567(2.3)	174(1.4)			
Insurer(n, %)								
NHI	478,871(50.5)	470,142(45.5)	133,840(97.9)	153,419(97.2)	18,609(6.1)	13,715(5.2)	12,231(96.8)	
EHI	460,287(49.0)	258,576(55.5)	2,919(2.1)	4,445(2.8)	757(3.9)	1,461(1.8)	4,070(3.2)	
PSQI score(means, sd)					4,612(5.5)	4,52(2.6)	4,62(5.5)	

Table 1. Background of the population, kencom® registrants, and PSQI respondents:

The kencom® registrants/PSQI respondents were younger, predominantly male, and mostly EHI members (vs. overall population). Participation increased, but demographics and mean PSQI remained stable.

Association between PSQI and QOL Scores by Survey	Crude β (95% CI)	p-value	Adjusted β (95% CI)*	p-value
2021 -0.0161 (-0.0166, -0.0156)	<0.001	-0.0153 (-0.0158, -0.0148)	<0.001	

Association between Changes in PSQI and QOL Scores

Change (2021-2022) -0.0079 (-0.0088, -0.0071) <0.001 -0.0105 (-0.0116, -0.0093) <0.001

Adjusted for covariates

Table 2. Association between PSQI and QOL Scores (2021, 2022, and change (2021-2022):

Poorer sleep quality (PSQI) was significantly associated with lower quality of life (QOL) in both cross-sectional (2021, 2022) and longitudinal (2021-2022 changes) analyses.

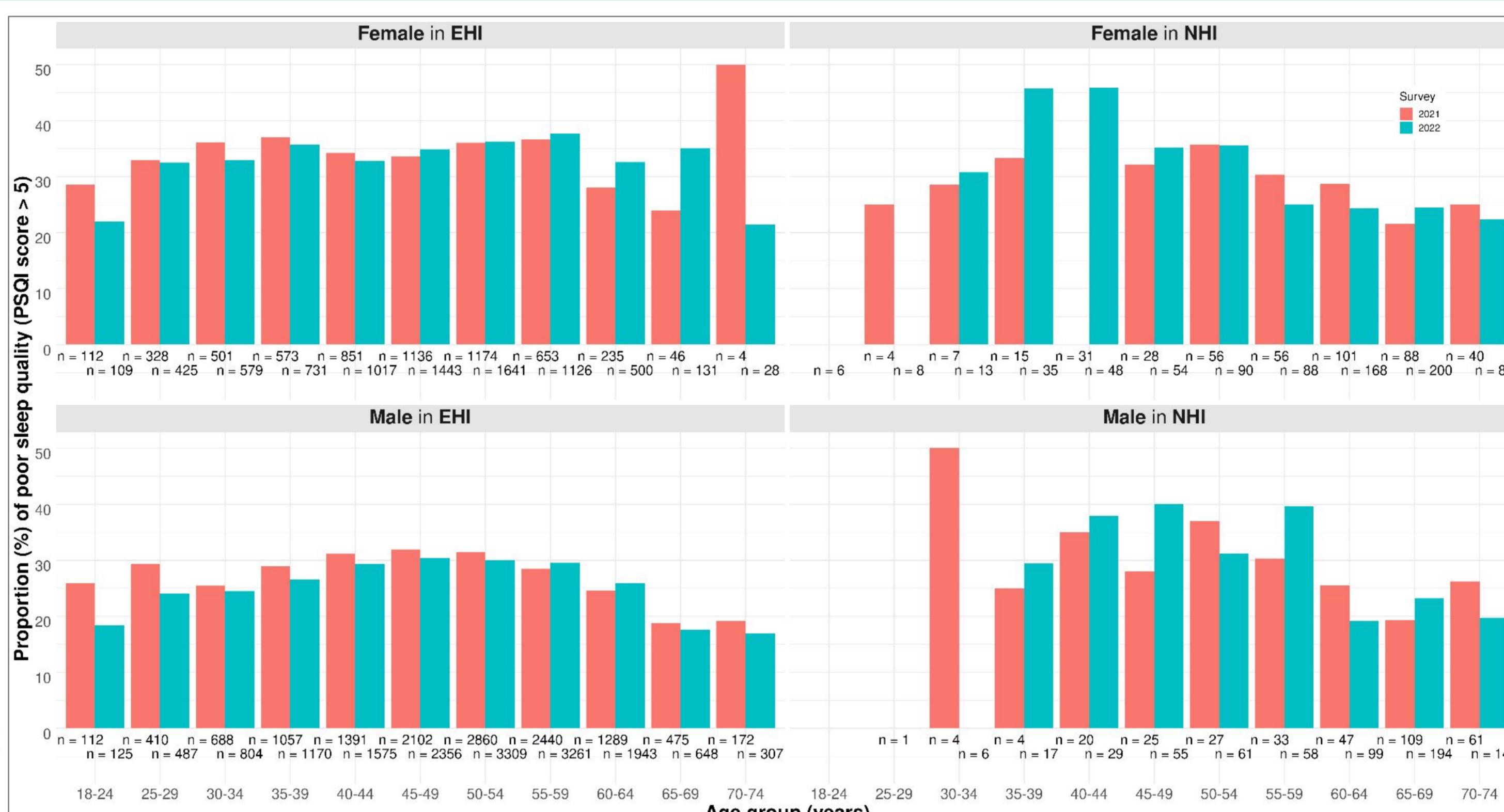


Figure 1. Proportion of poor sleep quality (PSQI score > 5) according to PSQI by survey and insurer type:

Contrary to general expectations, the proportion of poor sleep quality was lower in older adults compared to younger and middle-aged groups. This trend was consistent across both surveys, with the proportion of poor sleepers peaking in middle age and decreasing after age 60.

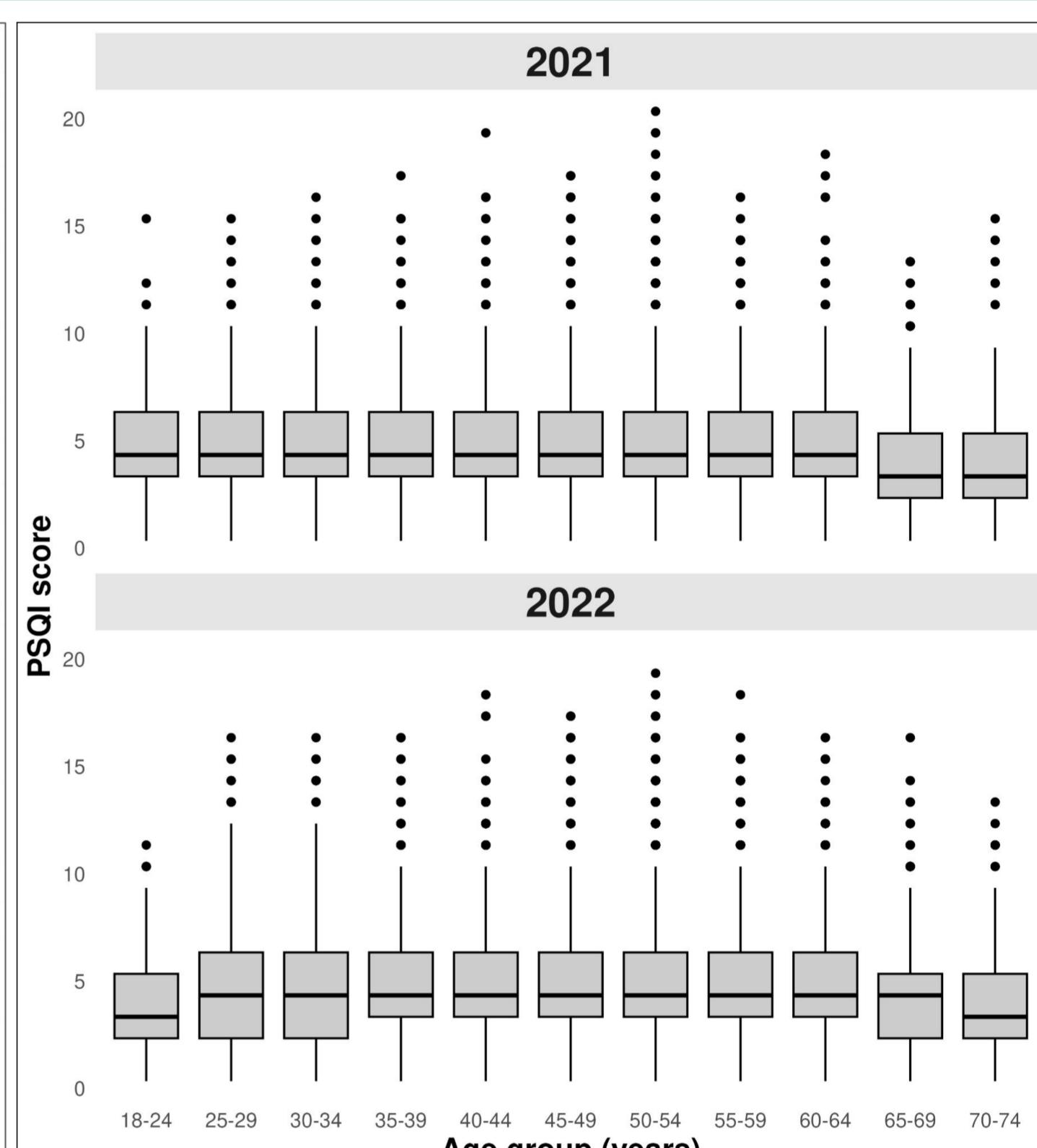


Figure 2. PSQI score distribution by survey: The data distributions look consistent across all age groups, with several outliers identified. Furthermore, no major differences were found between the two survey periods.

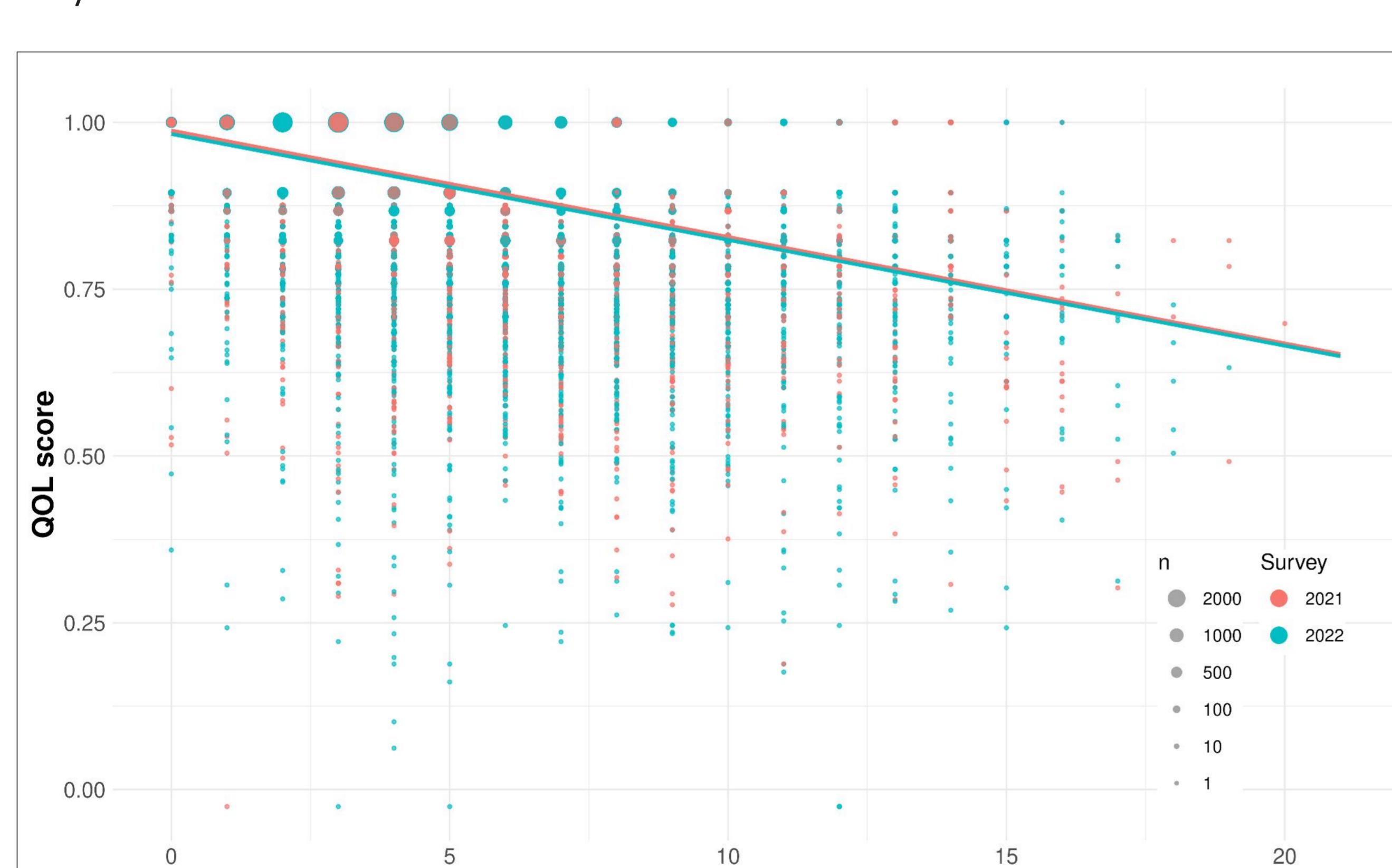


Figure 3. Relationship between PSQI and QOL scores by survey:

A significant negative correlation was found between PSQI and QOL scores, indicating that poorer sleep quality is associated with a lower QOL. This relationship remained consistent and highly significant across both the 2021 and 2022 surveys.

Discussion

- Non-elderly adults showed a higher proportion of poor sleep (high PSQI) compared to elderly adults. A Japanese national survey shows a similar trend as well.
- Strengths:** Innovative Data Linkage: The study linked large-scale PRO data (from tens of thousands of users) with administrative claims data.
- Limitations:** Selection Bias: The study population was limited to users of the kencom® app, which may affect the generalizability of the results.

Conflict of Interest

- Sado, Izutsu, and Hatakama are employed by DeSC Healthcare.
- Igarashi has received a joint research grant from DeSC Healthcare

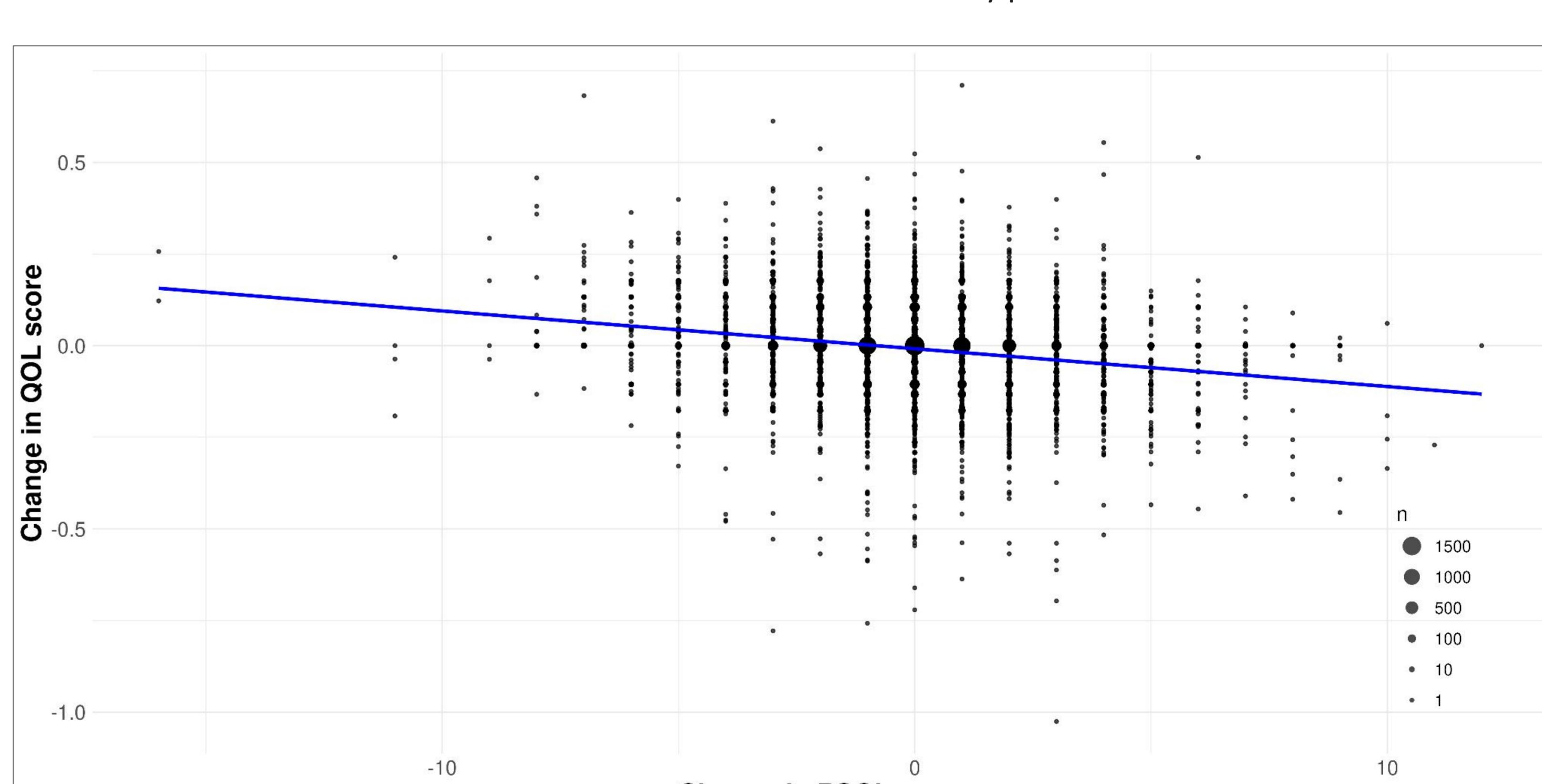


Figure 4. Relationship between Change in PSQI and QOL Scores:

A significant negative correlation was observed between the change in PSQI scores and the change in QOL scores. This indicates that an improvement in sleep quality (a decrease in PSQI score) is strongly associated with an improvement in Quality of Life (an increase in QOL score).

Conclusions

- PROs Visualize the Patient's Reality:** PRO data collected via smartphone apps visualize subjective health states not captured by claims data alone, demonstrating for the first time on a large scale the close link between sleep quality and QOL.
- Poor Sleep is a Sign of Low QOL:** Temporal changes in sleep quality were linked to changes in QOL, suggesting that early detection of and intervention for poor sleep are crucial for maintaining and improving patient QOL.