THE HUMANISTIC BURDEN OF FIBROMYALGIA IN JAPAN

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BACKGROUND

- The prevalence of fibromyalgia in Japan in 2011 was estimated to be 2.1% among adults (aged ≥20), with the majority (60.5%) of those affected being female.[1]
- In studies conducted in the US or EU, fibromyalgia was negatively associated with all dimensions of health-related quality of life (HRQoL), including poorer physical functioning, physical role functioning, general health, and sleep quality.[2,3]
- There is little research investigating the health burden of fibromyalgia in Japan. Most studies, to date, have been conducted in the US or EU, and it is unclear whether findings generalize to Japanese adults with fibromyalgia.

OBJECTIVES

- To examine the impact of fibromyalgia on HRQoL in Japanese adults.

METHOD

Study Design & Data Source

- Retrospective, cross-sectional database analysis using 2011 - 2014 data from the Japan National Health and Wellness Survey (NHWS), a representative, self-administered, internet-based questionnaire surveying adults in Japan aged 18 or older.

Sample

- Since it is possible for a respondent to complete more than one survey over this four-year period, only the most recent data for a given respondent will be kept in these instances (e.g., if a respondent participated in 2011 and 2013, only the 2013 data will be kept and used for analyses).
- All unique respondents from the 2011-2014 Japan NHWS were preliminarily included in the analyses (N=115,271).

Variables

Fibromyalgia

- Respondents who self-reported a diagnosis of fibromyalgia by a healthcare provider were considered to have fibromyalgia. All other respondents were considered not to have fibromyalgia (i.e., control respondents). A propensity score matching methodology was used to match fibromyalgia respondents with control respondents based on demographics and health characteristics.

Demographic and health characteristics

- Demographic characteristics included year of survey, gender, age, education, household income, and health insurance.
- Health characteristics included smoking habits, exercise behavior, alcohol use, body mass index (BMI), and the Charlson comorbidity index (CCI).

Health-Related Quality of Life

Health-Status

- Norm-based scores (mean=50, standard deviation=10) from the SF-36v2 (Medical Outcomes Study 36-Item Short Form Survey Instrument version 2; survey years 2012-2014) or SF-12v2 (survey year 2011) were calculated for:
  - The eight health domains: bodily pain, general health, mental health, physical functioning, role emotional, role physical, social functioning, and vitality.
  - The physical component summary (PCS) and mental component summary (MCS) scores.
- A health utility score derived from the SF-6D algorithm, with scores ranging from 0 (a health state equivalent to death) to 1 (a health state equivalent to perfect health).
- Minimally important differences (MIDs): 3 points for component summary scores, 5 points for health domains, and 0.041 points for health utilities.

Sleep difficulties

- The presence (or absence) of "difficulty falling asleep", "waking during the night and not being able to get back to sleep", "waking up several times during the night", and "poor quality of sleep" were assessed.

Statistical Analyses

- A greedy-matching algorithm was used to match respondents who self-reported a diagnosis of fibromyalgia (n=128) with those without fibromyalgia (n=128).
- One-way analysis of variance (continuous variables) or chi-square tests (categorical variables) were used to compare demographic and health characteristics between those with fibromyalgia and those without fibromyalgia (matched controls).
- Post-match, if any demographic or health characteristic variables differed between groups, then a series of generalized linear models were conducted to predict each outcome specifying the appropriate distribution (binomial for sleep difficulties due to binary responses on sleep items; normal for health status variables).
  - These models had fibromyalgia status (yes vs. no) as the primary independent variable and any variables which significantly differed between them as covariates.
  - Adjusted means and 95% confidence intervals were reported.
- Any two-sided p-values less than 0.05 were considered statistically significant.

RESULTS

Sample demographics and matching results

- Sample mean age was 44.5 years (SD=15.0); 62.5% were female.
- Of those who reported fibromyalgia (N=128), the average age was 42.62 (SD=14.34) years old; 59.4% were female (**Table 1**).
- At post-match, imbalance was observed between groups (standardized effect sizes >0.10, see **Table 1**). Therefore, age, gender, income, insurance, BMI categories, and exercise were used as covariates in multivariable analyses comparing outcomes between fibromyalgia and non-fibromyalgia.

Unadjusted comparisons

- Those with fibromyalgia vs. those without fibromyalgia had significantly lower HRQoL, including lower MCS, PCS, health utilities, and all of the health domain scores (e.g., bodily pain, role physical, vitality scale) (**Table 2**).
- Additionally, incidences of all sleep difficulties among those with fibromyalgia were also significantly higher than those without fibromyalgia (**Table 2**).

Adjusted comparisons

- After adjusting for covariates, results were consistent with unadjusted two-sample comparisons between those with fibromyalgia and those without the condition.
- Those with fibromyalgia compared with those without fibromyalgia had 12.72 points lower on MCS, 11.59 points lower on PCS and 0.185 points lower on health utilities, all p<0.001 (**Figure 1**).
- Additionally, all of the health domain scores were nearly 10 to 16 points lower for those with fibromyalgia compared with those without fibromyalgia, all p<0.001 (**Figure 1**).
- Differences on MCS, PCS, health utilities, and all of the health domains between those with fibromyalgia vs. those without fibromyalgia exceeded clinically meaningful levels.
- Relative to those without fibromyalgia, those with fibromyalgia experienced nearly 13 times the odds of waking during the night and not being able to get back to sleep and 7 times the odds of waking up several times during the night, all p<0.001 (**Figure 2**).

LIMITATIONS

- The study's results may be limited due to recall bias, given that outcomes were self-reported instead of clinically determined.
- Self-selection effects may likewise have biased results; younger, healthier, and/or wealthier respondents may have been more likely to participate in the study, as a function of greater access to the required technology and/or motivation to complete online surveys.
- Due to the cross-sectional, correlational design of this study, the results may not reflect longer-term changes in the burden of fibromyalgia, and causal inferences cannot be made.
- Finally, the NHWS is designed to be broadly representative of the Japanese adult population. Yet, the degree to which the NHWS represents the adult population with fibromyalgia cannot be confirmed.

CONCLUSIONS

- Compared with Japanese adults without fibromyalgia, those with fibromyalgia had lower scores on all SF-36/SF-12 subscales and differences far exceeded clinically meaningful levels.
- Similar to the substantial health burden associated with fibromyalgia reported in US studies, study findings revealed large decrements in health status and sleep quality among individuals with fibromyalgia in Japan.
- Improving the rates of diagnosis and treatment for this chronic pain condition may be helpful in addressing this considerable humanistic burden.

Table 1. Demographics and health characteristics by diagnosed fibromyalgia vs. non-fibromyalgia matched controls.

	Matched Controls (n=128)		Diagnosed Fibromyalgia (n=128)		P-Value	Standardized effect size
	Mean / %	SD / N	Mean / %	SD / N		
Age (mean, SD)	46.45	15.51	42.62	14.34	0.041	-0.26
Gender						
Female	65.6%	84	59.4%	76	0.302	-0.13
Male	34.4%	44	40.6%	52		
Annual household income						
<¥3 MM	39.1%	50	36.7%	47	0.902	-0.05
¥3 MM to <¥5 MM	17.2%	22	18.0%	23		0.02
¥5 MM to <¥8 MM	10.2%	13	14.1%	18		0.12
¥8 MM or more	28.9%	37	26.6%	34		-0.05
Decline to answer	4.7%	6	4.7%	6		-0.03
Insurance						
National Health Insurance	60.9%	78	53.1%	68	0.388	-0.16
Social Insurance	31.2%	40	34.4%	44		0.07
Late Stage Elderly Insurance	0.8%	1	0.0%[1]	0		-0.13
Other	3.1%	4	7.0%	9		0.18
None of the above	3.9%	5	5.5%	7		0.05
BMI categories						
Underweight	20.3%	26	15.6%	20	0.776	-0.12
Acceptable risk	39.8%	51	39.8%	51		0.00
Increased risk	21.9%	28	25.8%	33		0.09
High risk	12.5%	16	14.8%	19		0.07
Unknown	5.5%	7	3.9%	5		-0.12
Exercise behavior						
Exercise: 0 times	61.7%	79	56.2%	72	0.374	-0.11
Exercise: 1+ times 20 mins. in the past month	38.3%	49	43.8%	56		

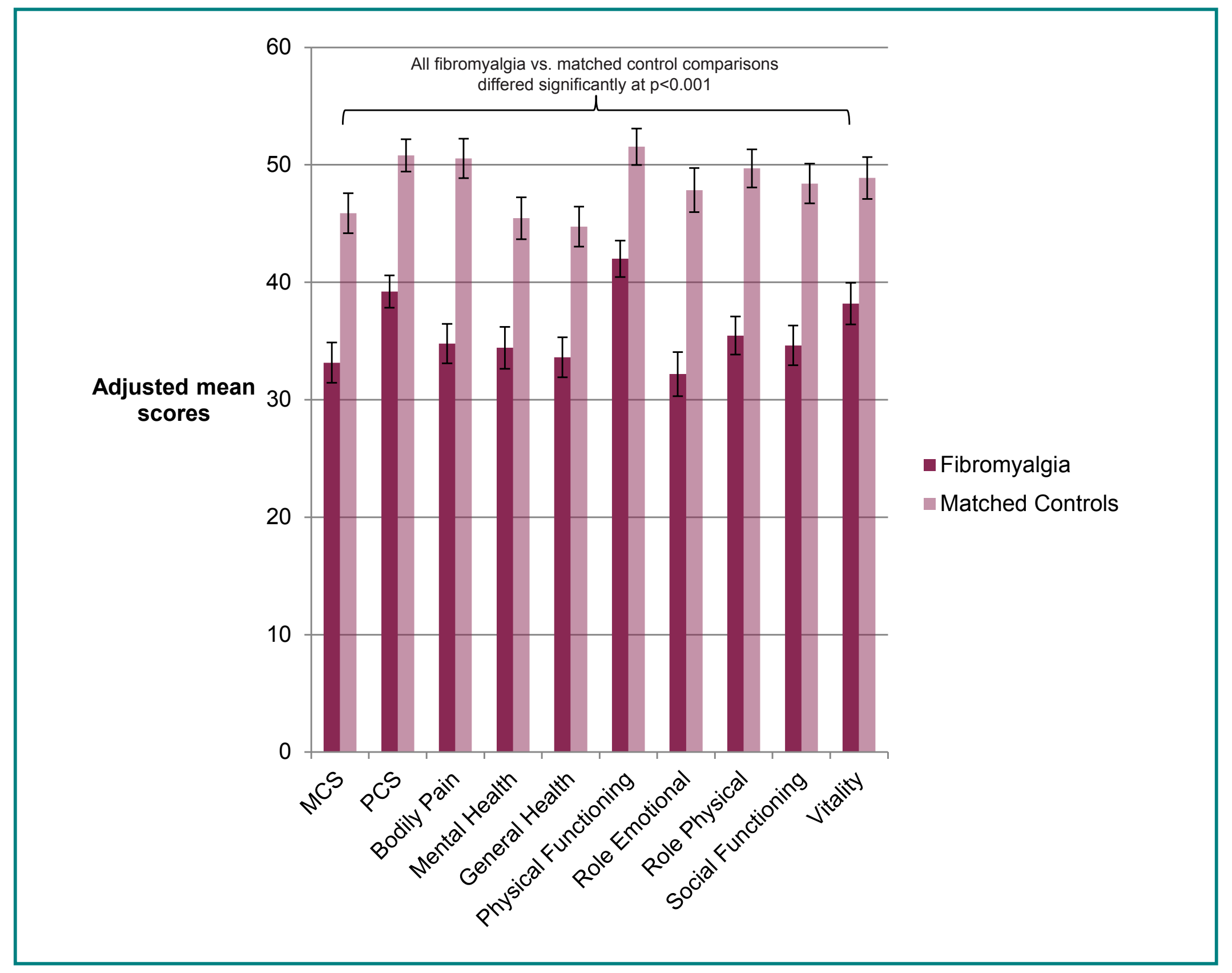
Note. [1]This category is not used in comparisons because its column proportion is equal to zero or one.
Abbreviations: SD= standard deviation; BMI= Body mass index; MM= million.

Table 2. Health-related quality of life by diagnosed fibromyalgia vs. non-fibromyalgia matched controls: Unadjusted results

	Matched Controls (n=128)		Diagnosed Fibromyalgia (n=128)		P-Value
	Mean / %	SD / N	Mean / %	SD / N	
SF-36v2/SF-12v2 Scores	46.45	15.51	42.62	14.34	0.041
Mental Component Summary	46.36	10.52	32.67	11.81	<0.001
Physical Component Summary	50.6	7.92	39.43	9.02	<0.001
SF-6D: Health State Utility Score	0.74	0.13	0.54	0.11	<0.001
Health Domain: Bodily Pain Scale	50.45	9.17	34.89	11.30	<0.001
Health Domain: General Health Scale	44.34	10.52	34.02	11.14	<0.001
Health Domain Mental Health Scale	45.96	11.13	33.92	12.04	<0.001
Health Domain: Physical Functioning Scale	51.73	8.37	41.81	10.99	<0.001
Health Domain: Role Emotional Scale	48.24	11.03	31.80	13.22	<0.001
Health Domain: Role Physical Scale	49.79	9.54	35.38	10.90	<0.001
Health Domain: Social Functioning Scale	48.82	10.09	34.22	11.27	<0.001
Health Domain: Vitality Scale	48.89	10.93	38.18	11.49	<0.001
Sleep Difficulties					
Difficulty falling asleep (%, N)	20.3%	25	52.6%	60	<0.001
Waking during the night and not being able to get back to sleep (%, N)	6.5%	8	36.0%	41	<0.001
Waking up several times during the night (%, N)	6.5%	8	32.5%	37	<0.001
Poor quality of sleep (%, N)	19.5%	24	44.7%	51	<0.001

Note. SF-36v2 was used in survey years 2012-2014; SF-12v2 was used in survey year 2011.

Figure 1. Adjusted means of SF-36v2/SF-12v2 component summary and domain scores by diagnosed fibromyalgia vs. non-fibromyalgia matched controls.

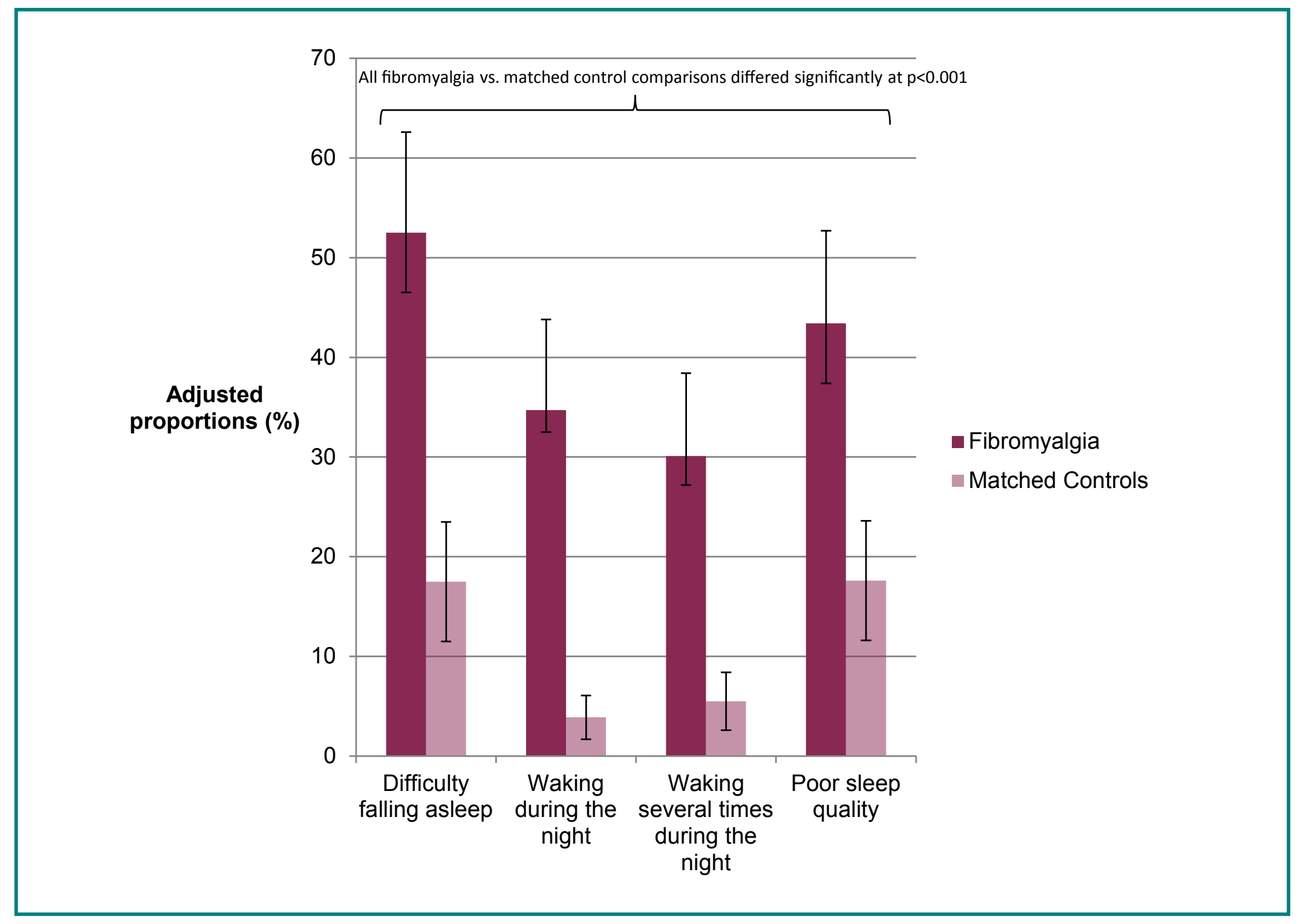


Notes. Generalized linear models, specifying a normal distribution and an identity function, were conducted. All models adjusted for age, gender (male vs. female), income (<¥3 MM, ¥3 MM - 5 MM, ¥5 MM – 8 MM, declined to answer vs. ¥8 MM or more), BMI (underweight, increased risk, high risk, unknown vs. acceptable risk), exercise (0 times vs. 1+ times) and insurance type (social health, late stage elderly/other, none vs. national health insurance). Error bars depict 95% confidence intervals.

SF-36v2 was used in survey years 2012-2014; SF-12v2 was used in survey year 2011.

Abbreviations: MCS= mental component summary; PCS= physical component summary.

Figure 2. Adjusted proportions for sleep difficulties (% experienced) by diagnosed fibromyalgia vs. non-fibromyalgia matched controls.



Notes. Generalized linear models, specifying a binomial distribution and a logit function, due to its binary nature were conducted. All models adjusted for age, gender (male vs. female), income (<¥3 MM, ¥3 MM - 5 MM, ¥5 MM – 8 MM, declined to answer vs. ¥8 MM or more), BMI (underweight, increased risk, high risk, unknown vs. acceptable risk), exercise (0 times vs. 1+ times) and insurance type (social health, late stage elderly/other, none vs. national health insurance). Error bars depict 95% confidence intervals.

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