

## ORIGINAL ARTICLE

# Effect of implementing an overwork-prevention act on working hours and overwork-related disease: A mediation analysis

Ro-Ting Lin<sup>1</sup>  | Ying-Wen Liang<sup>2</sup> | Masaya Takahashi<sup>3</sup>  | Hisashi Eguchi<sup>4,5</sup>  | Akizumi Tsutsumi<sup>4</sup>  | Sheng-Hsuan Lin<sup>2,6</sup> 

<sup>1</sup>Department of Occupational Safety and Health, College of Public Health, China Medical University, Taichung, Taiwan

<sup>2</sup>Institute of Statistics, National Chiao Tung University, Hsinchu, Taiwan

<sup>3</sup>Research Center for Overwork-Related Disorders, National Institute of Occupational Safety and Health, Kawasaki, Japan

<sup>4</sup>Department of Public Health, Kitasato University School of Medicine, Sagami-hara, Japan

<sup>5</sup>Department of Mental Health, Institute of Industrial Ecological Sciences, University of Occupational and Environmental Sciences, Institute of Industrial Ecological Sciences, Kitakyushu, Japan

<sup>6</sup>Institute of Data Science and Engineering, National Chiao Tung University, Hsinchu, Taiwan

## Correspondence

Sheng-Hsuan Lin, Institute of Statistics, National Chiao Tung University, Room 415, Assembly Building I, 1001 University Road, Hsinchu 30010, Taiwan. Institute of Data Science and Engineering, National Chiao-Tung University, Hsinchu, Taiwan  
Email: shenglin@stat.nctu.edu.tw

## Funding information

China Medical University, Taiwan, Grant/Award Number: CMU 108-MF-09; Ministry of Science and Technology, Taiwan, Grant/Award Number: 107-2314-B-039 -062 -MY3 and 108-2636-B-009 -001

## Abstract

**Objectives:** Overwork has been recognized as a risk factor for cerebrovascular and cardiovascular disease (CCVD). To our best knowledge, Japan is the first country in the world to implement an independent act (the 2014 Act) for the prevention of overwork-related disease, which was promoted through application of preventive measures, such as reductions in working hours. We assessed changes in working hours and overwork-related CCVD before and after introduction of the 2014 Act.

**Methods:** We calculated the overwork-related CCVD incidence rate and average monthly working hours for 10 industry groups in Japan with data from 2012 to 2018. We applied a causal mediation analysis to estimate the total effect of implementing the 2014 Act on the overwork-related CCVD and the effect mediated by working hours.

**Results:** An average of 271 for every 48 million employees developed overwork-related CCVD per year. After introducing the 2014 Act, the incidence rate ratio of overwork-related CCVD was 0.881-fold lower (95% CI 0.780-0.995) compared with before the policy change. The 2014 Act contributed to a decrease of 26% (78 cases per year; 95% CI 29-173) of the overwork-related CCVD incidence per year. Approximately 41% (32 cases per year) of this effect could be explained by reduced working hours.

**Conclusions:** Our study highlights the impact of the 2014 Act in Japan on the reduction in working hours, which further contributes to the reduction in overwork-related CCVD. Policymakers should consider adopting our innovative approach to assess the mediation effect underlying the implementation of new policies.

## KEYWORDS

cerebrovascular and cardiovascular disease, health policy, mediation analysis, overwork, prevention, working hours

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.

© 2020 The Authors. *Journal of Occupational Health* published by John Wiley & Sons Australia, Ltd on behalf of The Japan Society for Occupational Health

## 1 | INTRODUCTION

Working long hours has become a common phenomenon in East Asian societies, and it represents a polarization that has begun to occur across industries and occupations over the past years.<sup>1,2</sup> Moreover, these long working hours are a known cause of cerebrovascular and cardiovascular diseases (CCVDs).<sup>3</sup> The underlying mechanisms that link long working hours to CCVD development include psychosocial, behavioral, and biological risk factors.<sup>4</sup>

Japan is the first country in the world to officially recognize long working hours as a type of overwork.<sup>5</sup> Since 2001, new time frame has been applied to the recognition criteria for overwork-related CCVDs.<sup>6</sup> Specifically, employees are eligible for applying compensation if they meet the following criteria: working 45 hours of overtime per month during the 6 months preceding the onset of CCVD, 80 hours per month during the 2-6 months prior to the event, and 100 hours during the month prior to the event.<sup>6,7</sup> The inclusion of the above criteria in the recognition guideline increased the rate of recognized overwork-related CCVD by 2.8-fold and has thereby helped workers to receive compensation more smoothly.<sup>8</sup> Since then, however, the number of recognized cases has remained at approximately 300 cases every year.<sup>9</sup> Such a high and stable incidence could be due to the lack of a comprehensive regulatory and monitoring framework for overwork prevention.<sup>7</sup>

To prompt the society and companies to actively implement preventive measures against overwork, the Japanese government introduced the Act on Promotion of Preventive Measures against Karoshi (or death from overwork) and other Overwork-Related Health Disorders in June 2014 (2014 Act, hereafter), which took effect in November 2014.<sup>10</sup> In accordance with Article 7 of the 2014 Act, the Japanese government established an Outline for the Measures to Prevent Karoshi,<sup>10</sup> which addresses the need for reducing working hours and increasing the number of annual leaves given to employees, focusing on those who work overtime.<sup>11</sup> The number of working hours constitutes a specific, observable, and measurable indicator of the risk of overwork and CCVD.<sup>12,13</sup> The understanding of how the number of working hours influences the effectiveness of such a policy change on the incidence of overwork-related CCVD is the premise of continuous improvement. However, the extent to which policy changes influence rates of overwork-related CCVD through reduction in working hours remains unknown.

In this study, our objective was to investigate the effect of Japan's 2014 Act on the number of recognized overwork-related CCVD cases and determine how that effect was mediated by reductions in working hours. We aimed to test the hypothesis that the overwork-prevention policy reduced the number of overwork-related CCVD cases and that such a reduction could be attributed to the reduced working hours

resulting from implementation of the 2014 Act. We identified variations in the average number of working hours and incidence rates of overwork-related CCVD across at the industry level. We also estimated the mediation effect through the reduction in working hours on the incidence rate of overwork-related CCVD.

## 2 | METHODS

### 2.1 | Study design and data sources

The exposure of interest was the enforcement of the 2014 Act. To obtain a sufficient number of data points for longitudinal analysis, data were collected from the 3 years (2012-2014) before the introduction of the 2014 Act and from the period ranging from the date of its implementation to the most recent year of observation (2015-2018). The introduction of 2014 Act is a binary variable which takes value of 0 or 1. It equals 0 before or in 2014, and it equals 1 after 2014. We began with data from the year 2012 to avoid interference from different employment conditions before the Japan 311 earthquake, which occurred in 2011.

The unit of our analysis was the industry sector. The definition of industry sector was based on the Japan Standard Industrial Classification 11th and 12th revisions, which use 18 and 19 industry sectors, respectively.<sup>14</sup> We first excluded sectors with incomplete yearly data (agriculture, forestry, fishery, mining and quarrying of stone and gravel, and government) and then classified the remaining sectors into 10 industry groups according to data availability.<sup>14</sup> These groups were as follows: (1) construction; (2) manufacturing; (3) information and communications; (4) transportation and postal activities; (5) wholesale and retail trade; (6) finance and insurance; (7) accommodation, eating, and drinking services; (8) education and learning support; (9) medical, health care, and welfare, and (10) others—electricity, gas, heat supply, and water; real estate and goods rental and leasing; scientific research, professional and technical services; living-related and personal services and amusement services; compound services; and other services.

We obtained an annual summary of statistics published from 2012 to 2018 for 10 industry groups in Japan on the number of overwork-related CCVD cases, number of working hours, and information for other covariates (eg, salary and unemployment rate) to serve as proxy indicators of working conditions.<sup>8</sup> All variables were reported on the calendar year basis (from January 1 to December 31), except for the number of CCVD cases on the fiscal year basis (from April 1 to March 31). We used overwork-related CCVD cases that were recognized by the government as the outcome of interest and working hours as the mediator, defined as the average number of the sum of regular and overtime working hours by

industry group. The causal relationships of the implementation status of Japan's enforcement of the 2014 Act with working hours and number of overwork-related CCVD cases are assumed and demonstrated by a direct acyclic graph in Figure 1. Other covariates, including salary and unemployment rate, were adjusted as baseline confounders, which are described in our previous paper.<sup>8</sup> We obtained annual data on the number of recognized overwork-related CCVD cases, number of employees, average working hours per month, average salary per month, and unemployment rates for each industry sector from the Ministry of Health, Labour and Welfare of Japan.<sup>9,15</sup>

## 2.2 | Statistical analysis

We estimated the effect of enforcing the 2014 Act on overwork-related CCVD incidence rates (total effect) and investigated the mechanism in relation to working hours by conducting a causal mediation analysis. Causal mediation analysis is a statistical method to quantify the importance of a mediator among the causal mechanism of exposure on outcome.<sup>16</sup> Technically, causal mediation analysis decomposes the total effect of exposure (the 2014 Act) on outcome (overwork-related CCVD incidence rates) into two paths: (a) the path through the reduction in working hours (mediation effect, also referred to as the indirect effect), and (b) the path not through the change in working hours (alternative effect, also referred to as the direct effect). The ratio of mediation effect over total effect is termed as proportion mediated (PM). PM is interpreted as the proportion of a total effect which is explained by the involvement of a mediator. It is a popular indicator for the importance of the mediator among a total effect.

Statistical models for both the numbers of overwork-related CCVD cases and working hours were constructed for evaluating all effects. The first model regressed the numbers of overwork-related CCVD cases (dependent variable) on the independent variables, including the implementation status of the 2014 Act, salary, and unemployment rate (Model 1), whereas the second model further included working hours as an independent variable (Model 2). Because the number of overwork-related CCVD cases was in the form of count data, we applied Poisson regression for Model 1 and Model 2 with the annual number of employed person per year for each

industry group as the offset. The third model was constructed for working hours as the dependent variable (Model 3). These models can be described as follows:

$$\begin{aligned} \log E [\text{CCVD} | \text{the 2014 national Act, salary, unemployment rate}] \\ = a_0 + a_1 \times \text{national Act} + a_2 \times \text{salary} + a_3 \times \\ \text{unemployment rate} + \log \text{ person per year} + a_{0i} \end{aligned} \quad (1)$$

$$\begin{aligned} \log E [\text{CCVD} | \text{the 2014 national Act, working hours, salary, unemployment rate}] \\ = b_0 + b_1 \times \text{national Act} + b_2 \times \text{working hours} + b_3 \times \text{salary} + b_4 \\ \times \text{unemployment rate} + \log \text{ person per year} + b_{0i} \end{aligned} \quad (2)$$

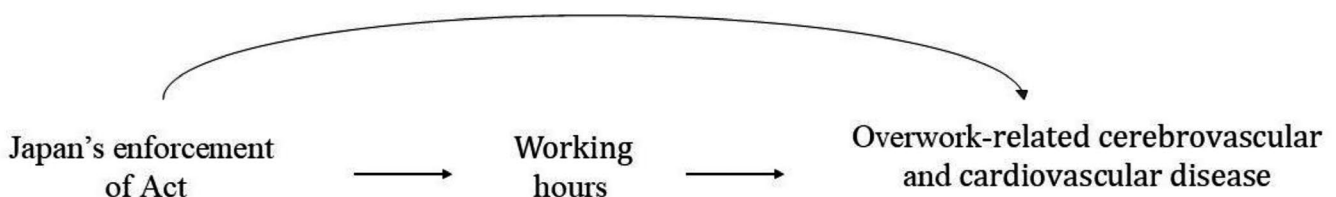
$$\begin{aligned} E [\text{working hours} | \text{the 2014 national Act, salary, unemployment rate}] = c_0 + c_1 \\ \times \text{national Act} + c_2 \times \text{salary} + c_3 \times \text{unemployment rate} + c_{0i} \end{aligned} \quad (3)$$

Because all variables for each industry group were collected repeatedly over the course of 7 years, mixed-effect models were constructed to correct autocorrelation within individual groups by adding random effects on intercepts ( $a_{0i}$ ,  $b_{0i}$ , and  $c_{0i}$ , assumed to be normally distributed) for each model. All analyses were performed on R version 3.4.3, and causal mediation analysis was conducted with mediation.R package, which was developed by Tingley et al.<sup>17</sup>

## 3 | RESULTS

Table 1 lists the averages for study indicators across the 10 industry groups before and after the enforcement of the 2014 Act. The average number of hired employees in each industry group increased by 6%, from 4.62 million to 4.91 million. The average number of working hours in each industry group per month decreased by 2.54 hours, from 145.91 to 143.37. The average incidence rate of overwork-related CCVD in each industry group decreased by 23%, from 6.54 to 5.04 per million employees.

Table 2 presents the estimates for all coefficients in two Poisson regression models that adopt CCVD as a dependent variable, one model with and one without working hours as the independent variable. In Model 1, which did not include working hours as the predictor, the enforcement of the 2014 Act significantly reduced the incidence rate ratio (IRR) of overwork-related CCVD from 1 to 0.782 ( $=e^{-0.246}$ )



**FIGURE 1** Causal relationship among Japan's enforcement of 2014 national Act (exposure), working hours (mediator), and incidence of overwork-related cerebrovascular and cardiovascular disease (outcome)

**TABLE 1** Averages<sup>a</sup> of indicator characteristics across 10 industries before and after the enforcement of the 2014 Act for overwork prevention

Indicator	Before the 2014 Act (2012-2014)		After the 2014 Act (2015-2018)	
	Mean (Min-Max)	Median (Q1-Q3)	Mean (Min-Max)	Median (Q1-Q3)
Number of hired employees (thousands)	4622 (1415-8703)	3615 (2653-7858)	4908 (1418-9024)	3921 (2851-8053)
Working hours per month	145.9 (104.6-173.9)	147.6 (136.0-163.0)	143.4 (101.4-171.2)	144.9 (135.3-163.2)
Salary per month (thousands Japanese yen) <sup>b</sup>	325.5 (132.1-510.2)	310.9 (280.8-386.9)	317.9 (127.7-490.6)	303.7 (275.5-382.0)
Unemployment rate (%)	2.0 (1.3-4.0)	2.0 (1.6-2.3)	2.0 (1.1-4.2)	2.0 (1.6-2.3)
Rate of overwork-related cerebrovascular and cardiovascular diseases <sup>c</sup>	6.5 (0.9-30.2)	4.7 (4.5-6.3)	5.0 (0.6-29.4)	3.4 (3.2-3.9)

<sup>a</sup>Weighted by the number of employees.<sup>b</sup>Adjusted by consumer price index.<sup>c</sup>Unit: annual cases per million employees.**TABLE 2** Coefficients in regression models estimated using incidence of overwork-related cerebrovascular and cardiovascular diseases as the dependent variable

	Model 1: not including working hours as the predictor				Model 2: including working hours as the predictor			
	Estimate	Lower 95% CI	Upper 95% CI	P value	Estimate	Lower 95% CI	Upper 95% CI	P value
Intercept	-12.113	-14.718	-9.509	<.001	-11.388	-13.283	-9.494	<.001
2014 Act (before vs after)	-0.246	-0.345	-0.148	<.001	-0.127	-0.248	-0.005	.041
Working hours					1.069	0.476	1.663	<.001
Salary	-1.607	-7.447	4.232	.59	-5.836	-10.119	-1.552	.008
Unemployment rate	0.167	-0.305	0.638	.488	0.516	0.008	1.023	.046

Abbreviation: CI, confidence interval.

**TABLE 3** Coefficient estimations in the regression model using working hours as the dependent variable

	Estimate	Lower 95% CI	Upper 95% CI	P value
Intercept	-1.026	-2.245	0.192	.099
2014 Act (before vs after)	-0.083	-0.118	-0.047	<.001
Salary	3.601	0.832	6.37	.011
Unemployment rate	-0.098	-0.255	0.059	.222

Abbreviation: CI, confidence interval.

(95% confidence interval [CI] = 0.708 to 0.862) (regression coefficient = -0.246, 95% CI = -0.345 to -0.148), indicating a 22% decrease. When the model is conditioned on working hours (Model 2), the enforcement of the 2014 Act was significantly associated with a decrease in the IRR of overwork-related CCVD from 1 to 0.881 ( $=e^{-0.127}$ ) (95% CI = 0.780 to 0.995) (regression coefficient = -0.127, 95% CI = -0.248 to -0.005), indicating a 12% decrease. The number of working hours is also a significant predictor of overwork-related CCVD. Every additional hour of work in an industry group is associated with increase in the IRR

of overwork-related CCVD by 2.91-fold ( $=e^{1.069}$ ) (95% CI = 1.610 to 5.275) (regression coefficient = 1.069, 95% CI = 0.476 to 1.663).

Table 3 presents estimates for the coefficients in the regression model that uses working hours as the dependent variable. The enforcement of the 2014 Act was significantly associated with the reduction in the average working hours per month across industry groups (coefficient = -0.083, 95% CI = -0.118 to -0.047). Salary was also a positive predictor of working hours (coefficient = 3.601, 95% CI = 0.832 to 6.37).

The result of the causal mediation analysis is shown in Table 4. The total effect of the enforcement of the 2014 Act is associated with the decrease in incidence of overwork-related CCVD of 1.580 cases per million employees annually (95% CI = 0.595 to 3.529). The effect not through the reduction in average working hours reduced the incidence rate of overwork-related CCVD by 0.927 cases per million employees annually (95% CI = 0.020 to 2.168). The effect through reducing working hours led to a decrease of 0.653 cases per million employees annually (95% CI = 0.148 to 1.955). The proportion mediated by working hours accounted for 41%. By using the annual average of total hired employees

**TABLE 4** Parameter estimates of total, mediation, and alternative effects of the enforcement of the 2014 Act on the incidence rate of overwork-related cerebrovascular and cardiovascular disease

Effect	Estimate	Lower 95% CI	Upper 95% CI	P value
Total effect	-1.580	-3.529	-0.595	<.001
Mediation effect (mediated by working hours)	-0.653	-1.955	-0.148	<.001
Alternative effect (not mediated by working hours)	-0.927	-2.168	-0.020	.045

Note: Unit was "average number of annual cases per million employees" in additive scale (Incidence Rate Difference).

Abbreviation: CI, confidence interval.

in these 10 industry groups (which was 49,082,348 between 2015 and 2018) as the reference population, an estimated 78 overwork-related CCVD cases were prevented per year due to the enforcement of the 2014 Act, among which 32 cases were attributable to the reduced working hours resulting from enforcement of the new 2014 Act. The 78 cases accounted roughly 26% of the average number of overwork-related CCVD cases per year before 2014 Act (2012-2014).

## 4 | DISCUSSION

Japan has long been viewed as the country with overwork culture and longest working hours, with 63% of workers working 35-60 hours per week and 8% more than 60 hours per week.<sup>18</sup> Our results indicated that the enforcement of the 2014 Act for overwork prevention contributed to preventing 1.58 of one million hired employees from developing CCVD. Given that the studied 10 industries employed an average of 49 million employees per year between 2015 and 2018, the 2014 Act can be considered to have prevented 78 cases of overwork-related CCVD. The passage of the 2014 Act demonstrates the effort made by Japan's government and its companies to prevent overwork and reduce working hours. The 2014 Act, as the overarching policy for overwork prevention, covered four nationwide strategies: (a) conducting research, (b) increasing awareness, (c) providing consultation services, and (d) supporting nongovernmental organizations' (NGOs) activities.<sup>11,19</sup> Step-by-step approaches to reducing working hours are promoted in Japan under these strategies.

Prevention of overwork-related diseases requires comprehensive policies that affect the multiple factors that mediate the effect of each policy. Mediators may affect policy effectiveness.<sup>20</sup> Long working hours can increase the risk of CCVD.<sup>12,21</sup> We considered working hours as potential mediators in our models. Our results reveal that the number of working hours is a significant predictor of overwork-related CCVD and that the reduction in working hours explains 41% of the mechanism, which prevented 32 people from developing CCVD. Our study evidenced the mediation effect of working hours on the association between policy enforcement and

overwork-related CCVD in Japan. One study that applied the mediation analysis to investigate the impact of revised recognized criteria on the incidence of overwork-related CCVD in Taiwan also reported reduced working hours as a significant mediation effect on the association.<sup>22</sup> The difference between Japan's 2014 Act and Taiwan's criteria change is the trend in the number of overwork-related CCVD. The implementation of Japan's 2014 Act led to a decreasing trend. The 2014 Act focuses on prevention, with one of the aims to increase public awareness of overwork prevention and health risks of long working hours. Government efforts could be reflected in the increasing national budget for actions to increase awareness of overwork prevention by 4.3-fold over the past 4 years (from 2.1 billion JPY in 2015 and increased to 9.1 billion JPY in 2018).<sup>18</sup> In contrast, the enforcement of new recognition criteria in Taiwan focused on expanding the scope of eligibility for compensation, resulting in an increase in the overall number of overwork-related CCVD cases. Similar to the effect of 2014 Act in Japan, the new criteria in Taiwan might also be attributed to the increasing awareness of the importance of reducing working hours in the process of recognizing overwork-related disease.<sup>22</sup> Findings for both situations evidenced that national policies are useful for reducing the incidence rate of overwork-related CCVD and that working hours are a significant mediator for the causal mechanism of this policy.

Considering that each increment in the average working hours of an industry group is associated with an increase in IRR of 2.9 for overwork-related CCVD in Japan, mitigating the risk of prolonged working hours should be a target for overwork prevention. According to one ecological study that used industry-level data in Taiwan, the number of working hours was a significant nonlinear predictor of different CCVD severity outcomes (death, disability, and illness).<sup>12</sup> When the number of monthly working hours increased by 18 hours (ie, from 169 to 187 hours), the risk of total overwork-related CCVD incidence increased by 4-fold (ie, from 1.5 to 5.7).<sup>12</sup> Each 1-hour decrease in working hours had a stronger effect on reducing the incidence rate of more severe CCVD outcomes (such as death) than on reducing that of mild outcomes (such as illness).<sup>12</sup>

Considering that approximately 41% of overwork-related CCVD cases are deaths in Japan,<sup>9</sup> we can expect that reducing working hours might have a greater impact on preventing CCVD-related death. Notably, the Japanese government has set several numerical targets as key performance indicators of the 2014 Act,<sup>23</sup> such as reducing the percentage of employees who work more than 60 hours per week to less than 5% by 2020. Recent amendments to the Japan's Labor Standards Act, which has come into effect on April 1, 2019, also include provisions (Article 36.5) that capped legal overtime at 45 hours per month and 360 hours per year for general situation and permitted an extension of up to 100 hours per month and 720 hours per year for busy periods for a maximum of 6 months per year.<sup>24</sup> A decreasing trend in the incidence of overwork-related CCVD in Japan is expected to continue in the foreseeable future.

Although working hours explains 41% of the mechanism, the remaining 59% of the effect of the 2014 Act on the decrease in the incidence of overwork-related CCVD cannot be explained by the reduction in working hours. The enforcement of the 2014 Act not only restricted overall working hours but also improved the quality of working environments, such as by limiting continuous long periods of work, night and shift work, irregular work schedules, and jobs with high psychological demand.<sup>6,19</sup> Among these risk factors, work-related stress and subsequent diseases have become more prevalent in Japan over the years.<sup>19,25</sup> In a multicohort study, Kivimaki and colleagues estimated that high job strain increased the risk of death from cardiometabolic diseases by 1.68-fold among male workers compared with those without job strain.<sup>26</sup> Furthermore, the 11th Revision of the International Classification of Diseases (ICD-11) includes burn-out as an occupational phenomenon by defining it is a syndrome conceptualized as resulting from chronic workplace stress that has not been successfully managed.<sup>27</sup> Our analysis showed that the increase in salary was significantly associated with the decrease in the incidence of overwork-related CCVD. However, salary was positively associated with working hours. Therefore, the mechanism not mediated by reduced working hours can probably be attributed to improvements in working environment resulting from the enforcement of the 2014 Act, which are not reflected by overall working hours. Another study is required to collect and investigate other potential mediators beyond those considered in the present study to understand the causal mechanism underlying the policy change.

Several limitations in this study should be noted before the results are further interpreted. First, we only considered salary and unemployment rate as confounders due to the restriction of data availability. However, there are several potential confounders, such as work-related mental health risks, that need to be included in this model in order to

obtain more accurate causal interpretation for our results. In addition, the mediation effect through working hours was statistically significant, accounting for 41% of the effects; however, more potential mediators should be considered, such as a continuous long work periods, night and shift work, irregular work schedules, and jobs with high psychological demands, in order to provide a more comprehensive understanding of all possible pathways. As mentioned earlier, the 2014 Act promotes four strategies (research, awareness, consultation services, and NGOs support), which is worth for a separate analysis investigating the pathway to effect policy. Moreover, this nationwide research was based on ecological data, which lack detailed information for each individual.<sup>28</sup> Thus, the result can only infer causality at the industry level rather than at the individual level. Incomplete data on some sectors (agriculture, forestry, fishery, mining and quarrying of stone and gravel, and government) reminded that our findings should be carefully interpreted. We should avoid extrapolating to industries not included in the analysis. Furthermore, although we excluded data in 2011 to avoid the interference from Japan 311 earthquake, this interference probably remains after 2012. We conducted sensitivity analysis by changing the years. Specifically, we conducted the causal mediation analysis based on the data from 2011 to 2018 (in Table S1) and on the data from 2013 to 2018 (in Table S2). The main findings remain (both total effect and mediation effects were significant, and the proportion mediated changes slightly). We also noticed that total effect declined after the earlier data were excluded. Finally, conducting randomized experiments on the influence of government measures or national act changes on individuals is impractical. Natural experimental and quasiexperimental designs can be alternatives to randomized experiments to differentiate the impacts of such events.<sup>29</sup> However, most changes to occupational health national acts apply to the entire population.

## 5 | CONCLUSION

In this study, we provide evidence that Japan's enforcement of the 2014 Act for overwork prevention contributed to a decrease of 26% of the overwork-related CCVD incidence per year. Approximately 41% of this effect could be attributed to the reduction in working hours. Our study also demonstrated an innovative approach for assessing the mediation effect underlying the enforcement of new policies.

## ACKNOWLEDGMENTS

We acknowledge the support of the Ministry of Science and Technology of Taiwan (MOST 108-2636-B-009 -001 to SHL and MOST 107-2314-B-039 -062 -MY3 to RTL) and the grant from China Medical University in Taiwan (CMU

108-MF-09 to RTL). We thank the editors at Tandem Editing LLC for their careful copyediting.

## DISCLOSURE

*Approval of the research protocol:* Our study involves comparison and analysis of variables at the population level (industry groups) rather than at the individual level. No personal data were handled. *Informed consent:* N/A. *Registry and the registration no. of the study/trial:* N/A. *Animal studies:* N/A.

## CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

## AUTHOR CONTRIBUTIONS

RTL contributed to the idea formulation, study design, data preparation, data analysis, reporting results, data interpretation, and writing of the manuscript. SHL contributed to data analysis, reporting of the results, data interpretation, and writing of the manuscript. YWL contributed to data analysis, reporting of the results, and writing of the manuscript. MT, HE, and AT contributed to writing of the manuscript. All authors participated in commenting on subsequent drafts, approved the final manuscript, and agreed to submit for publication.

## ORCID

Ro-Ting Lin  <https://orcid.org/0000-0002-2687-203X>

Masaya Takahashi  <https://orcid.org/0000-0003-1398-4347>

Hisashi Eguchi  <https://orcid.org/0000-0002-4153-8574>

Akizumi Tsutsumi  <https://orcid.org/0000-0003-0966-4869>

Sheng-Hsuan Lin  <https://orcid.org/0000-0003-0714-2354>

## REFERENCES

1. Tsai MC, Nitta M, Kim SW, Wang WD. Working overtime in East Asia: convergence or divergence? *J Contemp Asia*. 2016;46(4):700-722.
2. Yamauchi T, Sasaki T, Yoshikawa T, Matsumoto S, Takahashi M. Incidence of overwork-related mental disorders and suicide in Japan. *Occup Med*. 2018;68(6):370-377.
3. Bannai A, Tamakoshi A. The association between long working hours and health: a systematic review of epidemiological evidence. *Scand J Work Env Health*. 2014;40(1):5-18.
4. Virtanen M, Kivimäki M. Long working hours and risk of cardiovascular disease. *Curr Cardiol Rep*. 2018;20(11):7.
5. Park J, Kim Y, Cheng Y, Horie A. A comparison of the recognition of overwork-related cardiovascular disease in Japan, Korea, and Taiwan. *Ind Health*. 2012;50(1):17-23.
6. Labor Standards Bureau, Ministry of Health, Labour and Welfare. Recognition standards for cerebrovascular diseases, ischemic heart diseases, etc. (excluding those attributable to injuries). Notice No. 1063, issued on 12 December 2001. <http://www.mhlw.go.jp/new-info/kobetu/roudou/gyousei/rousai/dl/040325-11a.pdf>. Accessed March 26, 2017
7. Yamauchi T, Yoshikawa T, Takamoto M, et al. Overwork-related disorders in Japan: recent trends and development of a national policy to promote preventive measures. *Ind Health*. 2017;55(3):293-302.
8. Lin R-T, Lin C-K, Christiani DC, et al. The impact of the introduction of new recognition criteria for overwork-related cardiovascular and cerebrovascular diseases: a cross-country comparison. *Sci Rep*. 2017;7(1):167.
9. Ministry of Health, Labour and Welfare, Japan. Brain and cardiovascular diseases. <http://www.mhlw.go.jp/stf/houdou/>. Published 2012–2018. Accessed July 13, 2019.
10. Ministry of Health, Labour and Welfare, Japan. Act on Promotion of Preventive Measures against Karoshi and Other Overwork-related Health Disorders. Act No. 100. In:27 June 2014.
11. Ministry of Health, Labour and Welfare, Japan. 2015 Outline for the Measures to Prevent Karoshi. In: July 24, 2015.
12. Lin RT, Chien LC, Kawachi I. Nonlinear associations between working hours and overwork-related cerebrovascular and cardiovascular diseases (CCVD). *Sci Rep*. 2018;8:7.
13. Ono H. Why do the Japanese work long hours? Sociological perspectives on long working hours in Japan. *Japan Labor Issues*. 2018;2(5):35-49.
14. Ministry of Internal Affairs and Communications, Japan. Japan Standard Industrial Classification, Rev. 11 and Rev. 12. [http://www.soumu.go.jp/english/dgpp\\_ss/seido/sangyo/index.htm](http://www.soumu.go.jp/english/dgpp_ss/seido/sangyo/index.htm). Published 2002, 2007. Accessed February 28, 2019
15. Ministry of Health, Labour and Welfare, Japan. Labour statistics. <http://www.mhlw.go.jp/english/database/db-l/index.html>. Published 2012–2018. Accessed July 13, 2019.
16. VanderWeele T. *Explanation in Causal Inference: Methods for Mediation and Interaction*. Oxford: Oxford University Press; 2015.
17. Tingley D, Yamamoto T, Hirose K, Keele L, Imai K. Mediation: R package for causal mediation analysis. *J Stat Softw*. 2014;59(5):38.
18. Ministry of Health, Labour and Welfare, Japan. White papers on prevention of Karoshi. <https://www.mhlw.go.jp/stf/seisakunit/suite/bunya/0000138529.html>. Published 2015, 2016, 2017, 2018. Accessed July 22, 2019
19. Takahashi M. Sociomedical problems of overwork-related deaths and disorders in Japan. *J Occup Health*. 2019;61(4):269-277.
20. Richiardi L, Bellocco R, Zugna D. Mediation analysis in epidemiology: methods, interpretation and bias. *Int J Epidemiol*. 2013;42(5):1511-1519.
21. Kivimäki M, Jokela M, Nyberg ST, et al. Long working hours and risk of coronary heart disease and stroke: a systematic review and meta-analysis of published and unpublished data for 603,838 individuals. *Lancet*. 2015;386(10005):1739-1746.
22. Lin SH, Chou MY, Lin RT. Mediation analysis for new recognition criteria, working hours, and overwork-related disease: a nationwide ecological study using 11-year follow-up data in Taiwan. *BMJ Open*. 2019;9(7).
23. Ministry of Health, Labour and Welfare, Japan. 2018 outline for the measures to prevent karoshi. In:24 July 2018.
24. Ministry of Health, Labour and Welfare, Japan. Labor Standards Act. In:14 December 2018.
25. Nakao M. Work-related stress and psychosomatic medicine. *Biopsychosoc Med*. 2010;4(1):4.

26. Kivimäki M, Pentti J, Ferrie JE, et al. Work stress and risk of death in men and women with and without cardiometabolic disease: a multicohort study. *Lancet Diabetes Endo*. 2018;6(9):705-713.
27. World Health Organization. Burn-out an "occupational phenomenon": International Classification of Diseases. World Health Organization. [https://www.who.int/mental\\_health/evidence/burn-out/en/](https://www.who.int/mental_health/evidence/burn-out/en/). Published 2019. Accessed June 23, 2019
28. Schwartz S. The fallacy of the ecological fallacy - the potential misuse of a concept and the consequences. *Am J Public Health*. 1994;84(5):819-824.
29. Bor J. Capitalizing on natural experiments to improve our understanding of population health. *Am J Public Health*. 2016; 106(8):1388-1389.

## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

**How to cite this article:** Lin R-T, Liang Y-W, Takahashi M, Eguchi H, Tsutsumi A, Lin S-H. Effect of implementing an overwork-prevention act on working hours and overwork-related disease: A mediation analysis. *J Occup Health*. 2020;62:e12148. <https://doi.org/10.1002/1348-9585.12148>