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Subjective cognitive impairment and presenteeism mediate the associations of rumination with subjective well-being and ill-being in Japanese adult workers from the community

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Abstract

Background: In recent years, the roles of rumination, subjective cognitive impairment (SCI), and presenteeism have been emphasized in occupational mental health. However, associations between rumination, SCI, presenteeism, and psychological well-being are not fully understood. We hypothesized that SCI and presenteeism mediate the associations between rumination and subjective well-being (SWB) and subjective ill-being (SIB). Hence, we investigated the mediating roles of SCI and presenteeism in this study.

Methods: A total of 458 adult workers (mean age, 40.8±11.9 years; 44.1% male), who were recruited in Tokyo using convenience sampling, were analyzed in this study. The Ruminative Responses Scale, Cognitive Complaints in Bipolar Disorder Rating Assessment, Work Limitations Questionnaire 8, and Subjective Well-being Inventory were used to evaluate rumination, SCI, presenteeism, and psychological well-being (SWB and SIB), respectively. Path analyses were performed to evaluate the relations between these parameters.

Results: The path analysis indicated that rumination, SCI, and presenteeism were directly and negatively associated with SWB and SIB. Regarding indirect effects, rumination was negatively associated with SWB and SIB via SCI, presenteeism, and both SCI and presenteeism. Furthermore, SCI was negatively associated with SWB and SIB via presenteeism.

Conclusions: The results suggest that SCI and presenteeism mediate the associations of rumination with SWB and SIB in Japanese adult workers. To address the psychological well-being associated with rumination, evaluating SCI and presenteeism simultaneously may be useful in occupational mental health. This study provides key insights into the development of comprehensive intervention strategy based on the biopsychosocial perspective for worker's psychological well-being.

Keywords: Rumination, Subjective cognitive impairment, Presenteeism, Subjective well-being, Subjective ill-being, Mediator

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Background

“Good mental health” is defined as well-being that enables an individual to cope with life stress and work well [1]. In the present study, the concept of psychological well-being contains two independent dimensions—positive and negative affect, in other words, subjective well-being (SWB) indicates a positive state, while subjective ill-being (SIB) indicates a negative state that consists of negative psychological components, such as burnout and tiredness [2]. Notably, the deterioration of SIB does not necessarily lead to the decline of SWB and vice versa [3]. Thus, achieving good mental health should simultaneously be addressed from the viewpoints of SWB and SIB [4]. Furthermore, a recent study has insisted on the need for mental health screening and prevention by general practitioners because the current screening and prevention methods performed thus far may not be sufficient [5]. Indeed, individuals who later develop severe mental illness are rarely identified by current mental health services before they develop the illness, the rate of which is 5%–12% [6, 7]. In occupational mental health, addressing both the SWB and SIB of workers have been urgent issues in recent years.

Presenteeism indicates the state of being physically present at work, although the work productivity can be decreased by illness or other barriers to performance [8]. Presenteeism is considered an important intervention target in occupational mental health [9] because it is closely associated with a worker’s well-being [8, 10]. Various risk factors of presenteeism have been reported, including both physical and mental conditions [11]. Although a systematic review reported the influence of presenteeism on well-being [12], the relationships between the risk factors of presenteeism, SWB, and SIB are not well known.

Good cognitive function occupies a part of good mental health [1]. Cognitive impairment deteriorates psycho-social functioning not only in individuals with psychiatric illnesses but also in the nonclinical adult population [13, 14]. Cognitive function is divided into two categories: objective and subjective cognitive function. Objective cognitive function is primarily evaluated by neuropsychological tests whereas subjective cognitive function is primarily evaluated by self-administered questionnaires [13]. Notably, better subjective cognitive function correlates well with better mental health and higher social functioning [13]. Hence, in recent years, subjective cognitive function has come to be assessed more often in public and occupational mental health [13–15].

Rumination indicates repetitive and passive self-focused thoughts [16] and is positively correlated with objective cognitive dysfunction and depression [17]. Further, perseverative cognition via rumination affects both mental health and somatic symptoms [18]. Recent meta-analyses have highlighted the positive associations

among rumination with autobiographical memory specificity [19] and worse executive function [20]. As a result, rumination affects work productivity and mediates the influence of stressful work interruptions on psychosomatic symptoms [21, 22]. Additionally, a previous meta-analysis suggests that rumination is a mediator of the effect of mindfulness-based interventions and affects clinical outcomes [23]. A recent study has suggested the importance of interventions for work-related ruminative thinking [24]. Hence, evaluating rumination has become increasingly important in public health. Regarding the relation between rumination and psychological well-being, rumination predicted deteriorated SWB [25, 26] and SIB in workers [27]. Thus, rumination is considered a predictor of psychological well-being.

Subjective cognitive impairment (SCI) indicates perceived cognitive dysfunction in daily life [28], which is known to act as a mediator in the relation between some clinical parameters. In the general population, SCI mediates the effects of depressive symptoms on psycho-social function [13]. In Japanese adult workers, SCI mediates the association between depressive symptoms and presenteeism [14]. However, whether SCI and presenteeism mediate the associations of rumination with SWB and SIB in Japanese adult workers is not fully understood.

Rumination impacts internal attention switching and predicts SCI [29, 30]. Meanwhile, SCI negatively affects SWB [31] and is strongly associated with psychological distress and predicted deteriorated SIB [32, 33]. Both SCI and presenteeism are more likely to be detected in the workplace [13, 34]. Previous studies have reported that happier workers are more productive at work [35]. Mental conditions, such as depressive and anxiety symptoms, also affect work productivity [11]. Rumination is known to be a characteristic cognition common to depression and anxiety disorders [36]. Furthermore, rumination deteriorates SCI [29, 30], and SCI deteriorates SWB and SIB [31–33]. Therefore, based on these relationships, targeting cognitive dysfunction contributes to promoting psychological well-being [37]. A recent meta-analysis reported the effectiveness of psychological interventions to improve the SWB of workers [38]. Regarding the role of cognitive dysfunction of workers, SCI plays a mediating role in the relationship between insomnia, anxiety, or depressive symptoms and presenteeism [14, 39]. However, whether SCI mediates the relation between rumination and presenteeism is not well known to date.

From the aspect of path model, previous studies suggested the “rumination → cognitive dysfunction” model [40] as well as the “cognitive dysfunction → presenteeism” [14] and “presenteeism → well-being” [41] models. However, the “rumination → cognitive dysfunction → presenteeism → well-being” model has not been investigated; particularly, whether cognitive dysfunction and presenteeism can simultaneously mediate the

associations of rumination with SWB and SIB remains unknown.

The theoretical evidence for the present study can be described based on path models. First, rumination predicts SCI, and SCI predicts presenteeism, and presenteeism predicts SWB and SIB: “rumination→SCI” [29, 30], “SCI→presenteeism” [14], “presenteeism→SWB” [42], and “presenteeism→SIB” [43]. Taken together, we set “rumination→SCI→presenteeism→SWB and SIB” models. Second, rumination predicts both SWB and SIB: “rumination→SWB” [25, 26], “rumination→SIB” [27]. Rumination also predicts presenteeism, and SCI predicts SWB and SIB: “rumination→presenteeism” [44, 45], “SCI→SWB” [31], and “SCI→SIB” [32, 33]. Hence, regarding the “rumination→SCI→presenteeism→SWB and SIB” models, the direct effects on our path models were shown in these previous studies. However, the indirect effects of SCI and presenteeism in the relation between rumination and SWB or SIB have not yet been investigated.

Based on the theoretical evidence described above, we hypothesized that SCI and presenteeism mediate the relations between rumination and SWB and SIB. Hence, we performed the mediation analysis for SCI and presenteeism in the present study.

Methods

Participants

This cross-sectional study was conducted between April 2017 and April 2018 in Tokyo, Japan, in accordance with the Declaration of Helsinki. At the beginning of this research, the present study design was approved by the Local Ethics Review Board of Tokyo Medical University (Ethics Approval Number: SH3502).

During this period, a total of 597 subjects were recruited. The inclusion criteria were as follows: 20 years of age and older, no severe physical illnesses or brain damage, and agreed to participate in this research. This study obtained written informed consent at the beginning of the assessments. This research was part of a larger study, where several self-administered questionnaires were used [13]. The exclusion criteria of this study were as follows: being unemployed or not working during the assessment and not completing the questionnaires; hence, a total of 139 subjects were excluded and 458 subjects were analyzed in the present study.

Ruminative Responses Scale (RRS)

The RRS evaluates the severity of ruminative responses. It is composed of 22 items, each of which can be rated using a 4-point Likert scale from 1 (*Almost never*) to 4 (*Almost always*) [46]. The validity and reliability of the RRS have been previously shown, and the RRS has been confirmed to have adequate psychometric properties [47, 48]. In this study, we

assessed rumination using the Japanese version [49]. We calculated the RRS total score by summing each score. The higher the total score, the higher the ruminative response.

Cognitive complaints in bipolar disorder rating assessment (COBRA)

The COBRA evaluates SCI and is composed of 16 items, each of which can be rated using a 4-point Likert scale from 0 (*never*) to 3 (*always*) [28]. The validity and reliability of the COBRA have been shown, and the COBRA has been confirmed to have adequate psychometric properties [28]. The study participants used the Japanese version for which validity and reliability have been previously reported and which has been used in the general adult population [13, 50]. We calculated the COBRA total score by summing each score, with higher scores indicating more serious SCI. Furthermore, a total score ≥ 15 reflects moderate to severe SCI [13].

Work Limitations Questionnaire 8 (WLQ-8)

The WLQ-8 evaluates presenteeism. This questionnaire is composed of eight items, each of which is rated using the following Likert scale: *all of the time, a great deal of the time, some of the time, a slight bit of the time, none of the time, and does not apply to my job* [51–53]. The work productivity loss score, which reflects the % of presenteeism, was calculated by the weighted sum of the scores [14, 54]. Higher scores indicate more severe presenteeism.

Subjective Well-being Inventory (SUBI)

The SUBI evaluates SWB and SIB, which include 19 and 21 items, respectively [55]. A 3-point Likert scale from 1 to 3 was applied for each item, and the total SWB and SIB scores were calculated by summing the item scores. Higher scores indicate better statuses for both SWB and SIB. The Japanese version, whose reliability and validity have been previously reported, was used in this study [56, 57].

Statistical analysis

To evaluate the correlations among ruminative responses, SCI, presenteeism, SWB, and SIB, Pearson's correlation analysis using the Bonferroni method was performed. We performed multiple regression analyses using forced entry to investigate significant predictors of presenteeism, SWB, and SIB. We did not use the goodness-of-fit index because of the saturated models. To show the strengths of the effects, we calculated the standardized path coefficients in the path models. We performed all statistical analyses using STATA/MP 16 (Stata Corp LLC, College Station, TX, USA), except for the path analyses, which were conducted with Mplus version 8.4 (Muthén & Muthén, Los Angeles, CA, USA). For all analyses, the statistically significant level was set as $p < 0.05$.

Results

Basic findings

The participants' characteristics are displayed in Table 1. Nineteen subjects were receiving current psychiatric treatment, and 47 participants had a psychiatric history. Eighty-four participants were determined to have moderate to severe SCI.

The outcomes of Pearson's correlation analysis are shown in Additional file 1; all correlations were statistically significant. Rumination was positively correlated with SCI and presenteeism and negatively correlated with SWB and SIB. SCI was positively correlated with presenteeism and negatively correlated with SWB and SIB. Presenteeism was negatively correlated with SWB and SIB. SWB was positively correlated with SIB.

Multiple regression analysis

The outcomes of the multiple regression analysis are presented in Table 2. Rumination and SCI were significant positive predictors of presenteeism. Furthermore, rumination, SCI, and presenteeism were significant negative predictors of SWB and SIB.

Path analyses of SWB

The outcomes of the path analysis of SWB are presented in Table 3 and Figure 1, and all the paths were statistically significant.

There were positive direct effects of rumination on SCI and presenteeism and a negative direct effect on

SWB. Secondly, there was a positive direct effect of SCI on presenteeism and a negative direct effect on SWB. Finally, there was a negative direct effect of presenteeism on SWB.

There was a positive indirect effect of rumination on presenteeism via SCI. Second, there were negative indirect effects of rumination on SWB via SCI, via presenteeism, and via SCI and presenteeism. Finally, there was a negative indirect effect of SCI on SWB via presenteeism.

There was a positive total indirect effect of rumination on presenteeism and a negative total indirect effect on SWB. Further, there was a negative total indirect effect of SCI on SWB.

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The coefficients of determination (R^2) of SCI ($R^2 = 0.151$, $p < 0.001$), presenteeism ($R^2 = 0.238$, $p < 0.001$), and SWB ($R^2 = 0.146$, $p < 0.001$) were calculated in the path analysis (Figure 1).

Regarding the mediating effect, SCI mediated the effects of rumination on presenteeism and SWB, and presenteeism mediated the effects of rumination and SCI on SWB. Furthermore, SCI and presenteeism, in this turn, mediated the effect of rumination on SWB.

Path analyses of SIB

The outcomes of the path analysis of SIB are presented in Table 4 and Figure 2, and all paths were statistically significant.

There were positive direct effects of rumination on SCI and presenteeism and a negative direct effect on SIB. Secondly, there was a positive direct effect of SCI on presenteeism and a negative direct effect on SIB. Finally, there was a negative direct effect of presenteeism on SIB.

There was a positive indirect effect of rumination on presenteeism via SCI. Secondly, there were negative indirect effects of rumination on SIB via SCI, via presenteeism, and via SCI and presenteeism. Finally, there was a negative indirect effect of SCI on SIB via presenteeism.

There was a positive total indirect effect of rumination on presenteeism and a negative total indirect effect on SIB. Further, there was a negative total indirect effect of SCI on SIB. There were positive total effects of rumination on SCI and presenteeism and a negative total effect on SIB. Secondly, there was a positive total effect of SCI on presenteeism and a negative total effect on SIB. Finally, there was a negative total effect of presenteeism on SIB.

The coefficients of determination (R^2) of SCI ($R^2 = 0.151$, $p < 0.001$), presenteeism ($R^2 = 0.238$, $p < 0.001$),

Table 1 Demographic and clinical characteristics ($N = 458$)

Demographic characteristics	Mean (SD)	N (%)
Age (years)	40.8 (11.9)	
Sex (Male/Female)		202/256 (44.1/55.9)
Married		293 (64.0)
Number of cohabitants	2.9 (1.6)	
Education (years)	14.8 (1.8)	
Currently employed		458 (100)
Psychiatric history		47 (10.3)
Current psychiatric treatment		19 (4.2)
Drinking habit		301 (65.7)
Smoking habit		91 (19.9)
Clinical assessments	Mean (SD)	N (%)
RRS total score	35.5 (11.2)	
COBRA total score	8.5 (6.6)	
COBRA total score ≥ 15		84 (18.3)
WLQ work productivity loss score	0.04 (0.04)	
SUBI well-being score	38.4 (7.0)	
SUBI ill-being score	51.2 (6.3)	

Abbreviations: RRS Ruminative Responses Scale, COBRA Cognitive Complaints in Bipolar Disorder Rating Assessment, WLQ Work Limitations Questionnaire, SUBI Subjective Well-being Inventory, SD Standard deviation.

Table 2 Multiple regression analysis (N = 458)

Independent variables	WLQ F (2, 455) = 70.92, p < 0.0001		SUBI well-being F (3, 454) = 26.02, p < 0.0001		SUBI ill-being F (3, 454) = 97.40, p < 0.0001	
	β	VIF	β	VIF	β	VIF
RRS	0.22***	1.18	-0.20***	1.24	-0.41***	1.24
COBRA	0.36***	1.18	-0.12*	1.35	-0.26***	1.35
WLQ	-	-	-0.17**	1.31	-0.11**	1.31
Adjusted R²	0.23		0.14		0.39	

Abbreviations: β standardized regression coefficients, VIF variance inflation factor, R² Coefficient of determination. *p < 0.05, **p < 0.01, ***p < 0.001.

and SIB (R² = 0.393, p < 0.001) were calculated in the path analysis (Figure 2).

Regarding the mediating effect, SCI mediated the effects of rumination on presenteeism and SIB, and presenteeism mediated the effects of rumination and SCI on SIB. Furthermore, SCI and presenteeism, in this turn, mediated the effect of rumination on SIB.

Discussion

This study suggests that SCI and presenteeism mediate the associations of rumination with psychological well-being in adult workers. Our findings, which simultaneously report the mediating role of SCI and presenteeism on the relation of rumination with SWB and SIB, are novel.

Table 3 Standardized path coefficients of the path analysis of SWB (N = 458)

Direct effect to			
From	COBRA	WLQ	SUBI well-being
RRS	0.388***	0.222***	-0.199***
COBRA		0.357***	-0.123*
WLQ			-0.170***
Indirect effect to			
	COBRA	WLQ	SUBI well-being
RRS		0.139*** (via COBRA)	-0.048* (via COBRA) -0.038** (via WLQ) -0.024** (via COBRA and WLQ)
COBRA			-0.061** (via WLQ)
Total indirect effect to			
	COBRA	WLQ	SUBI well-being
RRS		0.139***	-0.109***
COBRA			-0.061**
Total effect to			
	COBRA	WLQ	SUBI well-being
RRS	0.388***	0.361***	-0.308***
COBRA		0.357***	-0.184***
WLQ			-0.170***

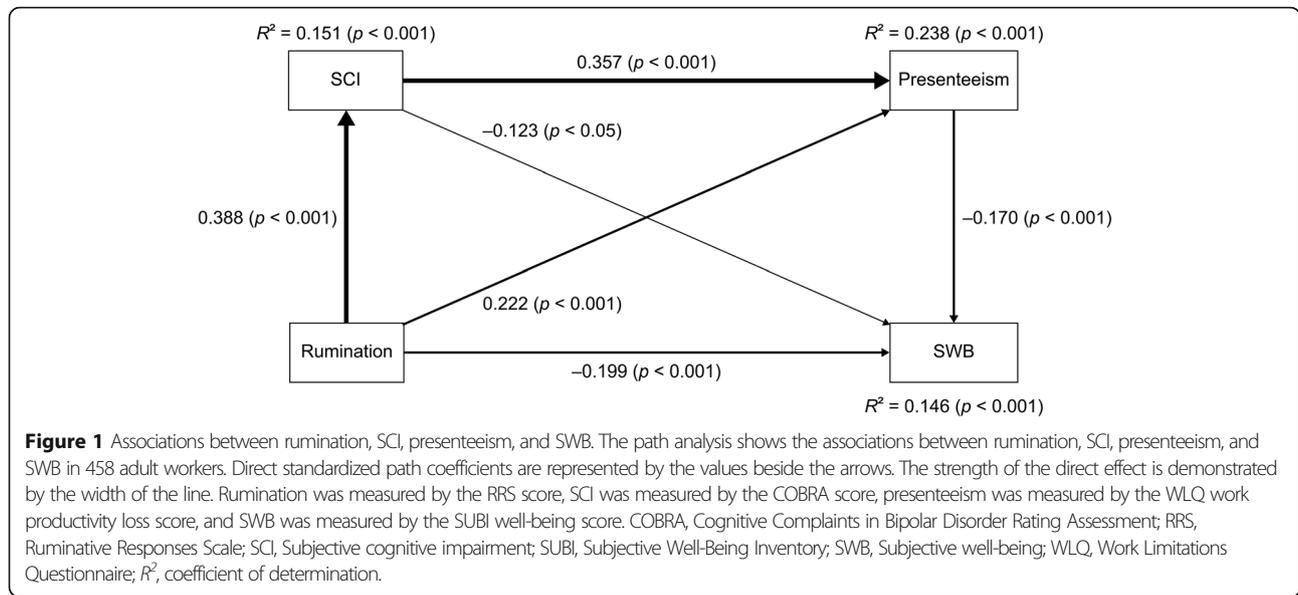
*p < 0.05, **p < 0.01, ***p < 0.001

First, the present study showed that SCI mediated the association between rumination and presenteeism. A previous study reported that SCI mediated the influence of depressive symptoms on presenteeism [14]. Although rumination is positively correlated with objective cognitive impairment and depression [17], the mediator role of SCI on the associations between rumination, depressive symptoms, and presenteeism has not yet been investigated simultaneously. To investigate these relations in greater detail, path analyses using the parameters of rumination, depressive symptoms, SCI, and presenteeism should be performed in the future.

Second, our findings suggest that SCI mediates the association between rumination and SWB. Previous research suggested that SCI mediated the relation between depressive symptoms and quality of life [13]. Furthermore, affective temperaments and personality traits affect SWB [4], and affective temperaments influence SCI [58, 59]. However, our path models did not include affective temperaments or personality traits, which could be a limitation. In the future, the genetic factors should be included in the path models.

Third, our results showed that SCI also mediated the correlation between rumination and SIB. A previous study has suggested that SCI mediates the relation between depressive symptoms and functional disability [13]. Depressive symptoms are positively correlated with rumination and SCI [13, 17], and depressive symptoms mediate the association between affective temperaments and SCI [58]. Furthermore, affective temperaments influence SIB, and SCI mediates the association between affective temperaments and functional disability [4, 59]. Hence, affective temperaments and depressive symptoms could play important roles in the mediating effect of SCI. However, affective factors were not evaluated in this study, which could be a limitation. In the future study, the biological and psychological affective parameters should be included in the path models.

Fourth, in our path models, presenteeism also mediated the associations between rumination, SCI, and SWB and SIB. This is a new finding that suggests the mediating effects of presenteeism on the relations between rumination, SCI, and SWB and SIB. A recent study



reported that presenteeism mediated the influence of workaholism on the conflict between work and family [60], and it also mediated the influence of job insecurity on psychological exhaustion [61]. Hence, the mediating role of presenteeism has attracted attention in occupational mental health. However, whether presenteeism

mediates the effects of rumination and SCI on work-family conflict or emotional exhaustion is not well known. Furthermore, whether presenteeism mediates the effects of workaholism and job insecurity on SWB and SIB is also not fully understood. In the future, those mediating effects should be investigated in larger longitudinal studies.

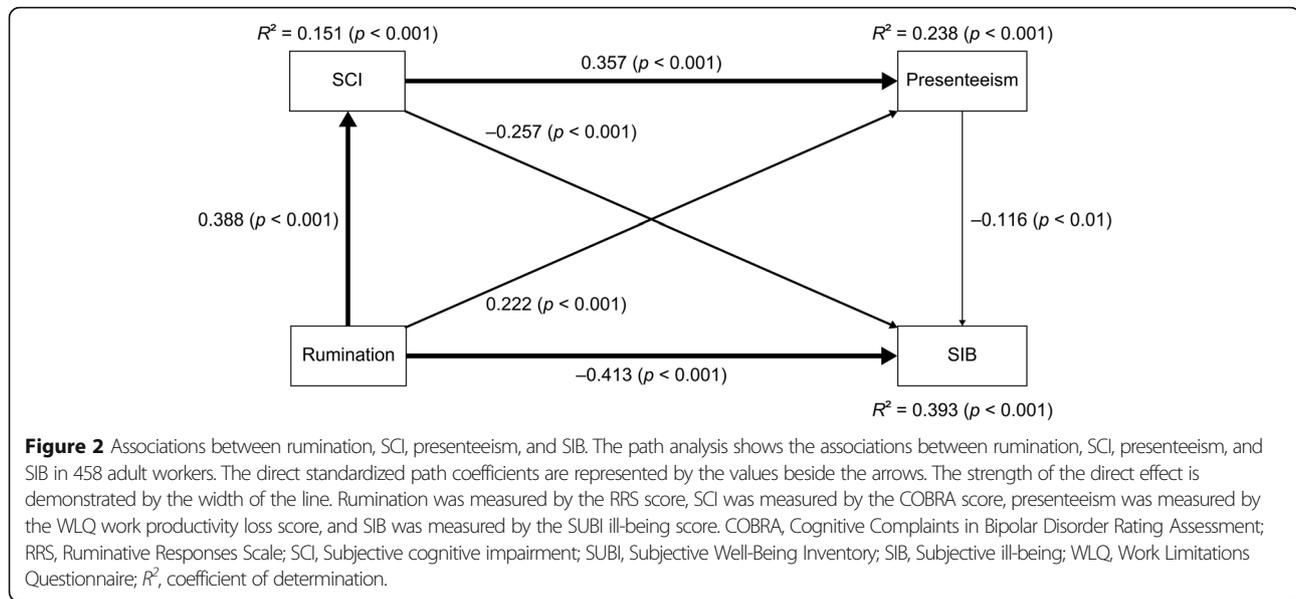
Table 4 Standardized path coefficients of the path analysis of SIB ($N = 458$)

Direct effect to			
From	COBRA	WLQ	SUBI ill-being
RRS	0.388***	0.222***	-0.413***
COBRA		0.357***	-0.257***
WLQ			-0.116**
Indirect effect to			
	COBRA	WLQ	SUBI ill-being
RRS		0.139*** (via COBRA)	-0.100*** (via COBRA) -0.026* (via WLQ) -0.016* (via COBRA and WLQ)
COBRA			-0.041** (via WLQ)
Total indirect effect to			
	COBRA	WLQ	SUBI ill-being
RRS		0.139***	-0.141***
COBRA			-0.041**
Total effect to			
	COBRA	WLQ	SUBI ill-being
RRS	0.388***	0.361***	-0.554***
COBRA		0.357***	-0.298***
WLQ			-0.116**

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Fifth, our findings highlighted the mediating roles of SCI and presenteeism, in this order, on SWB and SIB in adult workers from the community. Hence, to deal with SWB and SIB associated with rumination, evaluating both SCI and presenteeism simultaneously may be useful in occupational mental health. Previous studies reported a “depressive symptoms → SCI → presenteeism” model of adult workers [14], and a “depressive symptoms → SCI → quality of life” model of the general adult population [13]. Recent study showed a “trait anxiety → depressive symptoms → SCI → SIB” model of the general adult population [62]. The present study suggests a “rumination → SCI → presenteeism → psychological well-being” model of adult workers. Hence, to deal with deteriorated psychological well-being due to rumination, evaluating not only SCI and presenteeism but also depressive symptoms could be useful in occupational mental health.

Sixth, to address the psychological well-being of workers, cognitive behavioral therapy and mindfulness may be effective [38]. Rumination is one of the important factors that can aggravate treatment response for both cognitive behavioral therapy and mindfulness [23, 63]. To address this issue, rumination-focused interventions have recently been developed [64, 65]. Based on our findings and biopsychosocial perspective, the rumination-focused interventions could improve the psychological well-being of workers directly and



indirectly via SCI and presenteeism. In the future, we would like to conduct a longitudinal randomized controlled study to test this hypothesis.

Seventh, both SCI and presenteeism correlate well with mental health conditions, including insomnia, depressive symptoms, and state anxiety [14, 39]. According to our findings, both SCI and presenteeism are well associated with rumination and psychological well-being. Furthermore, the mediating roles of SCI and presenteeism in the associations of rumination and psychological well-being are indicated. Therefore, developing early interventions that target both SCI and presenteeism may be needed to deal with the declined psychological well-being due to rumination for adult workers.

Finally, regarding social factors, SCI correlates well with daily living [13] and presenteeism associates well with the working environment [34]. Hence, adjusting both living and working environments could be crucial to improve SCI and presenteeism simultaneously. We suggest that the comprehensive intervention strategy based on the biopsychosocial perspective needs to be developed to deal with psychological well-being associated with rumination in occupational mental health.

Limitations

This cross-sectional study could not evaluate the cause-and-effect relationships among the variables. We conducted convenience sampling for this exploratory study, which prevents the generalization of our findings. The present study included only workers, which prevents us from generalizing our findings to non-workers. Additionally, all participants in the present study were adults, which precludes the generalization of our findings to adolescents or children. Specifically, this study included

only adult workers, which precludes our findings from applying to underage workers. All the participants were Japanese, which prevents generalization of our results to individuals with different cultural backgrounds. The generalization of this study was also limited because study participants were recruited in Tokyo, where many office workers are employed. Hence, the difference between urban and rural areas could not be investigated. The influences of work specialty and workplace support on presenteeism were not assessed [34]. Both the individuals undergoing psychiatric treatment and healthy individuals were investigated together; hence, this heterogeneity could be a limitation. Further, the influence of current medication was not assessed or controlled for. Finally, memory bias could be a limitation because self-administered questionnaires were used to evaluate clinical characteristics in this study.

Conclusions

This study suggests that SCI and presenteeism mediate the relation of rumination with SWB and SIB in Japanese adult workers. Hence, evaluating the SCI and presenteeism simultaneously may be useful in occupational mental health. Furthermore, the comprehensive intervention strategy for the deteriorated psychological well-being may need to be developed from the biopsychosocial perspective. Our findings provide key insights into the worker's psychological well-being.

Abbreviations

COBRA: Cognitive Complaints in Bipolar Disorder Rating Assessment; RRS: Ruminative Responses Scale; SCI: Subjective cognitive impairment; SUBI: Subjective Well-Being Inventory; SWB: Subjective well-being; SIB: Subjective ill-being; WLQ: Work Limitations Questionnaire

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13030-021-00218-x>.

Additional file 1: Supplementary Table 1. Pearson's correlation analysis using the Bonferroni correction ($N = 458$). Description of data: Associations between rumination, subjective cognitive impairment, presenteeism, and subjective well-being and ill-being. The outcomes of Pearson's correlation analysis are shown in Additional file 1; all correlations were statistically significant. Rumination was positively correlated with SCI and presenteeism and negatively correlated with SWB and SIB. SCI was positively correlated with presenteeism and negatively correlated with SWB and SIB. Presenteeism was negatively correlated with SWB and SIB. SWB was positively correlated with SIB.

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Authors' contributions

K.T., M.I., T.I., and I.K. designed the study. K.T., M.I., T.I., A.S., J.M., Y.F., and S.H. collected and analyzed the data, and contributed to drafting the manuscript. I.K. supervised the preparation of the paper. All authors have read and agreed to the published version of the manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current research are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

This research was approved by the Local Ethics Review Board of the Tokyo Medical University (Ethics Approval Number: SH3502). All study procedures were carried out in accordance with the principles in Declaration of Helsinki. All subjects provided written informed consent after receiving an explanation about this research.

Consent for publication

All authors have given consent for publication.

Competing interests

M. I. received personal compensation from Otsuka Pharmaceutical, Pfizer, Eli Lilly, Mitsubishi Tanabe Pharma, Mochida Pharmaceutical, Meiji Seika Pharma, Janssen Pharmaceutical, Takeda Pharmaceutical, MSD, Dainippon Sumitomo Pharma, and Eisai; grants from Otsuka Pharmaceutical, Eli Lilly, Eisai, Shionogi, Takeda Pharmaceutical, MSD, and Pfizer; and is a member of the advisory board of Meiji Seika Pharma.

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