



## Subjective social status via mediation of childhood parenting is associated with adulthood depression in non-clinical adult volunteers



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### ABSTRACT

Subjective social status (SSS) is associated with major depression, but its association with depressive symptoms remains unknown. In this study, we hypothesized that SSS mediates the effects of the quality of parenting (care and overprotection) on self-esteem and depressive symptoms in adulthood in non-clinical self-selected adult volunteers, and this hypothesis was verified by covariance structure analysis. The following questionnaire surveys were conducted on 404 Japanese non-clinical adult volunteers: Patient Health Questionnaire-9 (PHQ-9), SSS, Parental Bonding Instrument (PBI), and Rosenberg Self-Esteem Scale (RSES). We conducted covariance structure analysis to elucidate the mediating effects of SSS on the effects of PBI on RSES and PHQ-9. In our models, self-esteem, but not the quality of parenting or SSS, directly deteriorated depressive symptoms. Poor quality of parenting in childhood indirectly exacerbated depressive symptoms through the mediating effects of SSS and self-esteem. This study showed that SSS is a mediator in the effects of the quality of parenting in childhood on adulthood depressive symptoms and self-esteem, and that self-esteem further mediates the effects of SSS. Our results may hence contribute to the elucidation of the association between SSS and depression.

### 1. Introduction

Major depressive disorder (MDD) is one of the most common psychiatric disorders, and its lifetime prevalence is 5%–17% in the general population (Sadock et al., 2014). The latest Global Burden of Disease Study reported that MDD is the second leading cause of years lived with disability (Global Burden of Disease Study 2013 Collaborators, 2015). Although many factors, such as inheritance, personality traits, experience in childhood, physical diseases, life events in adulthood, etc., affect depressive symptoms and are associated with the onset and course of MDD, their precise association with depressive symptoms remains unclear (American Psychiatric Association, 2013; Sadock et al., 2014). Moreover, several studies demonstrated that combinations of multiple factors further increase the risk of the onset of MDD and exacerbate depressive symptoms even in general adults (Caspi et al., 2003; Kendler et al., 2004; Nakai et al., 2015). In short, it is presumed that multiple factors interact to cause MDD and to increase depressive symptoms.

Recent studies have indicated that subjective social status (SSS) is associated with physical and psychiatric diseases and predicts future health conditions (Franzini and Fernandez-Esquer, 2006; Scott et al.,

2014; Singh-Manoux et al., 2005; Subramanyam et al., 2012). In the present study, SSS was evaluated by the following simple question: “If Japanese society was divided into 10 social strata, which stratum do you think you would belong to?” (Tsuno et al., 2015). The direct association between SSS and the prevalence of depression was reported in previous large-scale epidemiological studies on the general population (Hoebel et al., 2017; Scott et al., 2014). However, factors mediating or affecting this association remain to be elucidated.

Various studies have shown that both the quality of parenting in childhood and self-esteem are associated with the onset of MDD and the development of depressive symptoms (Parker et al., 1995; Sato et al., 2000; Sowislo and Orth, 2013). In these studies, the quality of parenting was assessed by the Parental Bonding Instrument (PBI), which is a self-reported questionnaire. Interactions among these factors may also affect depressive symptoms. For example, the quality of parenting in childhood (care and overprotection) affects depressive symptoms, trait anxiety, and various psychopathological symptoms through affecting self-esteem (Finzi-Dottan and Karu, 2006; Shimura et al., 2017; Valiente et al., 2014). On the other hand, SSS is reportedly correlated with self-esteem (Liu et al., 2017). Although there has been no research

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on the association of SSS with the quality of parenting or childhood abuse, objective socioeconomic status (OSS) was shown to be associated with childhood abuse and also affects adult general health, mental health, and well-being (Sheikh et al., 2016). In addition, SSS and OSS are associated with major depression/depressive symptoms to the same degree but the effect of SSS is partly independent of OSS (Hoebel et al., 2017; Scott et al., 2014; Subramanyam et al., 2012). The effects of SSS on subjective health are mediated by self-esteem (Kan et al., 2014). Therefore, there is the possibility that SSS may affect any point in the pathways by which the quality of parenting affects depressive symptoms through self-esteem.

In this study, we hypothesized that SSS and self-esteem act as mediators in the effects of the quality of parenting in childhood on depressive symptoms in non-clinical self-selected adult volunteers and verified this hypothesis by covariance structure analysis.

## 2. Methods

### 2.1. Subjects

We recruited Japanese non-clinical self-selected adult volunteers with flyers and word of mouth between January and August 2014. Flyers were distributed in Hokkaido University (Sapporo, Japan) through our acquaintances. This study was part of a larger study (Kanai et al., 2016). Of 853 subjects, 404 subjects (47.4%) agreed to participate in the study and provided complete responses to the paper-based questionnaire. Demographic characteristics (age, sex, years of education, employment status, current marital status, living alone or not, comorbidities of physical disease) and four questionnaires were distributed and returned anonymously. Written informed consent was obtained from all of the subjects after giving the following explanations: 1) their participation in this research is entirely voluntary, 2) if they decide not to participate, they are not in any disadvantage, and 3) the information that we collect from this research project will be kept completely confidential. In accordance with the Helsinki Declaration, this study was conducted with approval from the ethics committees of Tokyo Medical University and Hokkaido University Hospital.

### 2.2. Questionnaires

#### 2.2.1. Patient Health Questionnaire-9 (PHQ-9)

PHQ-9 is a 9-item self-completed questionnaire that screens major depressive episodes and measures the severity of depressive symptoms (Spitzer et al., 1999). We used the Japanese version of PHQ-9, which has been verified for its validity and reliability (Muramatsu et al., 2007). In this study, a summary score of PHQ-9 (0 to 27 points) was used for the analysis.

#### 2.2.2. Parental Bonding Instrument (PBI)

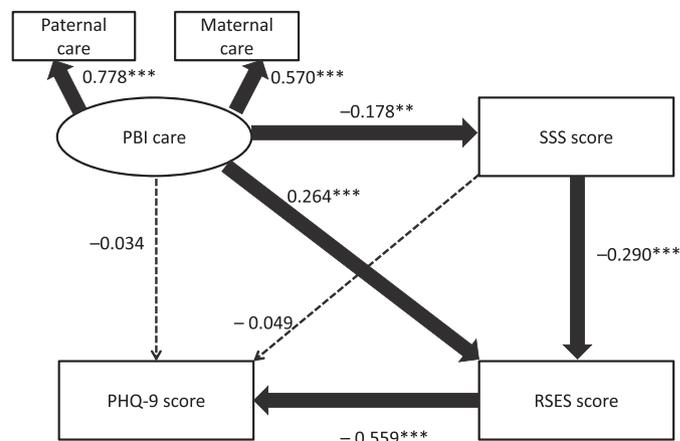
PBI is a self-completed questionnaire that retrospectively analyzes the quality of parenting or parental attitude toward the child until 16-years old (Parker et al., 1979). PBI consists of questions on two subscales of parental care and overprotection and evaluates fathers and mothers separately (Parker et al., 1979). The Japanese version of the PBI was used in this study, which has been verified for validity (Kitamura and Suzuki, 1993).

#### 2.2.3. Rosenberg Self-Esteem Scale (RSES)

RSES is a self-administered questionnaire consisting of 10 items to evaluate self-esteem (Rosenberg, 1965). A higher total score indicates higher self-esteem. In this study, we used the Japanese version of the RSES (Yamamoto et al., 1982).

#### 2.2.4. Subjective social status (SSS)

SSS is a subjective self-assessment scale to determine which hierarchical social level the subject thinks they are in. We defined 1 as the



**Fig. 1.** Results of covariance structure analysis in the structural equation model with the care subscale on the Parental Bonding Instrument (PBI care), the subjective social status (SSS) score (SSS score), and the score of the Rosenberg Self-esteem Scale (RSES) (RSES score), as well as depressive symptoms (PHQ-9 score) in 404 non-clinical self-selected adult volunteers. Rectangles indicate the observed variables, some of which are associated with the latent variable, which is shown as an oval. The arrows with solid lines represent statistically significant paths, and broken lines show the nonsignificant paths. Numbers beside the arrows show direct standardized path coefficients (minimum  $-1$ , maximum  $+1$ ), and indirect effects through variables are shown in the results section.  $**p < 0.01$ ,  $***p < 0.001$ .

highest social status level and 10 as the lowest social status level.

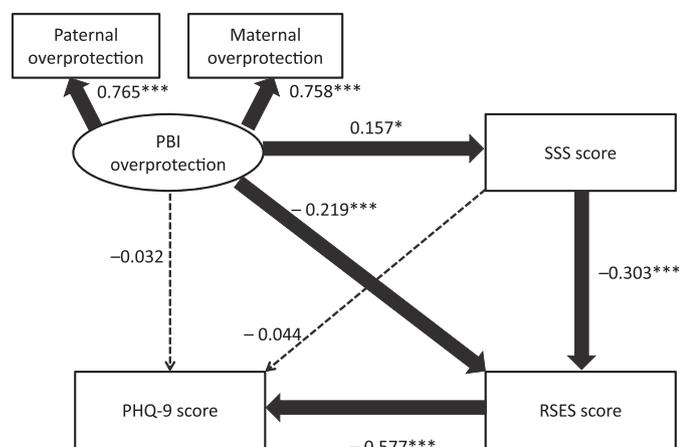
### 2.3. Data analysis

The Pearson correlation coefficient was determined and the unpaired *t*-test was performed using SPSS Statistics 22.0 J software (SPSS Chicago IL, USA), for calculating the correlation between variables and comparing demographic data between two categories (e.g., men vs women), respectively. Furthermore, to analyze whether the quality of parenting (PBI care and overprotection), SSS, and self-esteem (RSES score) affect depressive symptoms independently of other demographic variables, stepwise multiple regression analysis was performed, in which data from the demographic characteristics and questionnaires were independent variables and a summary score of the PHQ-9 was a dependent variable.

We designed the following two structural equation models (SEM), in which the depressive symptoms (PHQ-9 scores) were predicted by the quality of parenting (PBI care and overprotection), SSS, and self-esteem (RSES score), as shown in Figs. 1 and 2. Covariance structure analysis with the robust maximum likelihood estimation method was performed using Mplus version 7.3 software (Muthén & Muthén, Los Angeles, CA, USA), to analyze the complex associations and mediation effects. We defined two latent variables, namely, ‘PBI care’ and ‘PBI overprotection’ from observed variables of paternal and maternal scores. In this study, Comparative Fit Index (CFI) and Root Mean Square Error Approximation (RMSEA) were used for judging the goodness of fit of the model. A good fit was defined as a CFI  $> 0.97$  and RMSEA  $< 0.05$ , and an acceptable fit was defined as CFI  $> 0.95$  and RMSEA  $< 0.08$  (Schermelleh-Engel et al., 2003). All coefficients of the covariance structure analysis were standardized ( $-1$  to  $+1$ ).

Model 1 (Fig. 1): High care by parents in childhood increases SSS and self-esteem and decreases depressive symptoms. Care has indirect effects on depressive symptoms through effects on SSS and self-esteem. SSS has an indirect effect on depressive symptoms through the effect on self-esteem.

Model 2 (Fig. 2): The high overprotection by parents in childhood decreases SSS and self-esteem and increases depressive symptoms. Overprotection has indirect effects on depressive symptoms through the



**Fig. 2.** Results of covariance structure analysis in the structural equation model with the overprotection subscale on the PBI (PBI overprotection), the SSS score, and the RSES score, as well as depressive symptoms (PHQ-9 score) in 404 non-clinical self-selected adult volunteers. Rectangles indicate the observed variables, some of which are associated with the latent variable, which is shown as an oval. The arrows with solid lines represent the statistically significant paths, and the broken lines show nonsignificant paths. The numbers beside the arrows show direct standardized path coefficients (minimum -1, maximum +1), and indirect effects through variables are shown in the Results section. \* $p < 0.05$ , \*\*\* $p < 0.001$ .

effects on SSS and self-esteem. SSS has an indirect effect on depressive symptoms through the effect on self-esteem.

A  $p$ -value of less than 0.05 was considered to indicate a statistically significant difference between two groups.

### 3. Results

#### 3.1. Demographic characteristics and PHQ-9, SSS, PBI, and RSES scores of the subjects

Table 1 shows the demographic characteristics and the PHQ-9, SSS, PBI, and RSES scores of 404 non-clinical self-selected adult volunteers, the correlation of continuous variables with PHQ-9 scores, and the effects of categorical variables on PHQ-9 scores. High age, being male, and a married status were associated with low PHQ-9 scores, but no other demographic data were associated with PHQ-9.

PBI maternal care and PBI paternal care scores were negatively correlated with PHQ-9 scores. PBI maternal overprotection and PBI paternal overprotection scores were not significantly correlated with PHQ-9 scores. SSS scores were positively correlated with PHQ-9 scores; i.e., the lower the SSS, the stronger the depressive symptoms. RSES scores were negatively correlated with PHQ-9 scores; i.e., the higher the self-esteem, the lower the depressive symptoms.

The mean PHQ-9 summary score was 3.3, which is in the range of 0–4, indicating no depressive symptoms (Kroenke et al., 2001). However, 3 subjects were in the range for severe depressive symptoms (PHQ-9 summary scores of 20 or higher), 6 subjects were in the range for moderately severe depressive symptoms (PHQ9: 15–19), 18 subjects were in the range for moderate depressive symptoms (PHQ9: 10–14), 74 subjects were in the range for mild depressive symptoms (PHQ9: 5–9), and the other 303 subjects were in the range for no depressive symptoms according to the PHQ-9 summary score criteria proposed by Kroenke et al. (2001).

#### 3.2. Stepwise multiple regression analysis of PHQ-9 summary scores

Table 2 shows the results of stepwise multiple regression analysis of PHQ-9 summary scores. Thirteen independent variables were added to the analysis. The stepwise method identified three significant

**Table 1**  
Characteristics, PHQ-9, PBI, SSS, and RSES and their correlation with PHQ-9 or effects on PHQ in 404 non-clinical adult volunteers.

Characteristics or measures	Number or mean $\pm$ SD	Correlation with PHQ-9 ( $r$ ) or effect on PHQ scores (mean $\pm$ SD of PHQ-9, $t$ -test)
Age	42.3 $\pm$ 11.9	$r = -0.138^{**}$
Sex (male: female)	220: 184	Male 2.9 $\pm$ 3.6 vs female 3.8 $\pm$ 4.1* ( $t$ -test)
Education years	15.2 $\pm$ 2.0	$r = -0.049$ , n.s.
Employment status (employed: non-employed)	341: 56	Employed 3.3 $\pm$ 3.8 vs non-employed 3.6 $\pm$ 4.4, n.s. ( $t$ -test)
Current marital status (married: unmarried)	286: 115	Married 3.0 $\pm$ 3.7 vs unmarried 4.0 $\pm$ 4.1* ( $t$ -test)
Living alone (yes: no)	102: 294	Yes 3.6 $\pm$ 4.2 vs no 3.1 $\pm$ 3.7, n.s. ( $t$ -test)
Comorbidity of physical disease (yes: no)	83: 317	Yes 3.9 $\pm$ 4.1 vs no 3.1 $\pm$ 3.7, n.s. ( $t$ -test)
PHQ-9	3.3 $\pm$ 3.8	
PBI		
Maternal care	27.7 $\pm$ 6.7	$r = -0.104^*$
Paternal care	23.9 $\pm$ 7.3	$r = -0.168^{**}$
Maternal overprotection	10.2 $\pm$ 6.8	$r = 0.096$ , n.s.
Paternal overprotection	9.5 $\pm$ 6.1	$r = 0.085$ , n.s.
SSS	4.9 $\pm$ 1.5	$r = 0.143^{**}$
RSES	35.9 $\pm$ 7.0	$r = -0.555^{**}$

Data are presented as means  $\pm$  SD or numbers.

$r$  = Pearson correlation coefficient.

PHQ-9, Patient Health Questionnaire-9; PBI, Parental Bonding Instrument; SSS, subjective social status; RSES, Rosenberg Self-Esteem Scale; n.s., not significant. \* $p < 0.05$ , \*\* $p < 0.01$ .

**Table 2**

Results of stepwise multiple regression analysis of PHQ-9.

Independent factors selected by stepwise	Standardized partial regression coefficient (Beta)	$p$ -value	VIF
Age	-0.120	0.007	1.092
Comorbidity of physical disease	0.098	0.026	1.079
RSES	-0.546	<0.001	1.013
Adjusted $R^2 = 0.323$	$F = 61.204$ , $p < 0.001$		

Beta = standardized partial regression coefficient, VIF = variance inflation factor.

PHQ-9, Patient Health Questionnaire-9; PBI, Parental Bonding Instrument; SSS, subjective social status; RSES, Rosenberg Self-Esteem Scale.

Dependent factor: PHQ-9 summary score.

Thirteen independent factors: age, sex (male = 0, female = 1), education years, employment status (non-employed = 0, employed = 1), current marital status (unmarried = 0, married = 1), living alone (yes = 0, no = 1), comorbidity of physical disease (no = 0, yes = 1), PBI scores (maternal care, paternal care, maternal overprotection, paternal overprotection), SSS, and RSES.

independent variables predicting PHQ-9 summary scores; age, comorbidity of physical disease, and RSES score, and other variables were excluded from this model ( $F = 61.204$ ,  $p < 0.001$ , adjusted  $R^2 = 0.323$ ). This model explained 32.3% of the variability in PHQ-9 summary scores. Multicollinearity was denied. Notably, the four subscales of the PBI and SSS were not significant predictors of PHQ-9 summary scores in this multiple regression analysis.

#### 3.3. Analysis of structural equation model 1

In model 1, we defined ‘PBI care’ as the latent variable, which comprised two observed variables, namely, paternal and maternal care of the PBI (Fig. 1). Because the CFI was 1.000 and RMSEA was 0.000, a very good fit of model 1 was obtained. Standardized coefficients from

the latent variable ‘PBI care’ to two observed variables ‘paternal care’ and ‘maternal care’ were 0.778 and 0.570, respectively. In this model, ‘PBI care’ had a significantly negative effect on SSS scores, i.e., increased social status ( $-0.178, p < 0.01$ ), and exerted a positive effect on RSES scores ( $0.264, p < 0.001$ ), but there was no significant direct effect on PHQ-9 scores. SSS scores had no direct effects on PHQ-9 scores but significant negative effects on RSES scores ( $-0.290, p < 0.001$ ): i.e., the higher the SSS, the higher the self-esteem.

Regarding indirect effects, ‘PBI care’ showed significant indirect effects on RSES scores via the SSS score ( $0.052, p = 0.008$ ), but the indirect effects of ‘PBI care’ on PHQ-9 scores via the SSS scores were not significant ( $0.009, p = 0.294$ ). The indirect effects of ‘PBI care’ on PHQ-9 scores via RSES scores were significant ( $-0.148, p < 0.001$ ). In addition, the indirect effects of ‘PBI care’ on PHQ-9 scores via two paths, including SSS scores and RSES scores, were significant ( $-0.029, p = 0.011$ ). Finally, SSS scores showed significant indirect effects on PHQ-9 scores via RSES scores ( $0.163, p < 0.001$ ). The square of the multiple correlation coefficient ( $R^2$ ) of the summary score of the PHQ-9 in this model was 0.31, indicating that this model explained 31% of the variability in PHQ-9 summary scores.

In summary, high parental care in childhood reduced depressive symptoms indirectly through the effects on SSS and self-esteem. High SSS indirectly decreased depressive symptoms by increasing self-esteem.

### 3.4. Analysis of structural equation model 2

In model 2, we defined ‘PBI overprotection’ as the latent variable, which comprised two observed variables; paternal and maternal overprotection of the PBI (Fig. 2). As the CFI was 0.992 and RMSEA was 0.055, a good fit of model 2 was obtained. The standardized coefficients from the latent variable ‘PBI overprotection’ to two observed variables ‘paternal overprotection’ and ‘maternal overprotection’ were 0.765 and 0.758, respectively. In this model, ‘PBI overprotection’ had a significantly positive effect on SSS scores, i.e., decreased social status ( $0.157, p < 0.05$ ), and exerted negative effects on RSES scores ( $-0.219, p < 0.001$ ), but there was no significant direct effect on PHQ-9 scores. SSS scores had no direct effect on PHQ-9 scores but significantly negative effects on RSES scores ( $-0.303, p < 0.001$ ); i.e., the higher the SSS, the higher the self-esteem.

Regarding indirect effects, ‘PBI overprotection’ showed a significant indirect effect on RSES scores via SSS scores ( $-0.047, p = 0.036$ ), but the indirect effects of ‘PBI overprotection’ on PHQ-9 scores via SSS scores were not significant ( $-0.007, p = 0.352$ ). The indirect effects of ‘PBI overprotection’ on PHQ-9 scores via RSES scores was significant ( $0.126, p < 0.01$ ). In addition, the indirect effects of ‘PBI overprotection’ on PHQ-9 scores via two paths, including SSS scores and RSES scores, were significant ( $0.027, p = 0.04$ ). Finally, SSS scores showed significant indirect effects on PHQ-9 scores via RSES scores ( $0.175, p < 0.001$ ). The square of the multiple correlation coefficient ( $R^2$ ) of the summary score of the PHQ-9 in this model was 0.31, indicating that this model explained 31% of the variability in PHQ-9 summary scores.

In summary, high parental overprotection in childhood indirectly increased depressive symptoms through the effects on SSS and self-esteem. Low SSS indirectly increased depressive symptoms by decreasing self-esteem.

## 4. Discussion

The primary findings of this study were that the quality of parenting, care, and overprotection in childhood affects depressive symptoms indirectly through SSS and self-esteem. SSS mediated the effect of the quality of parenting on self-esteem and depressive symptoms in adulthood. Interestingly, self-esteem further mediated the mediating effect of SSS on depressive symptoms. These findings have not been

reported to our knowledge, and hence this study is the first to report the mediating effect of SSS on the effects of the quality of parenting in childhood on self-esteem and depressive symptoms in non-clinical self-selected adult volunteers.

Earlier studies reported that the effects of SSS and OSS on mental and physical health are mediated by various psychosocial resources, including self-esteem and psychosocial vulnerability (Cundiff et al., 2013; Kan et al., 2014). In non-clinical adult volunteers, patients of primary care clinics, and pregnant women, a low SSS was correlated with not only the degree of depressive symptoms, but also low self-esteem, high neuroticism, rumination, and emotional dysregulation, which may be involved in the association of low SSS with major depression and depressive symptoms (Cundiff et al., 2013; Fleuriet and Sunil, 2014; Talavera et al., 2017; Zvolensky et al., 2017). The SEM analysis of our present study first showed that self-esteem mediates the effects of SSS on depressive symptoms in non-clinical adult volunteers. In our SEM, it is noteworthy that the direct effect of SSS on depressive symptoms was not significant but only the indirect effect of SSS on depressive symptoms through self-esteem was significant. In other words, the mediating effect of self-esteem on SSS and depressive symptoms was complete mediation (Baron and Kenny, 1986). Besides self-esteem, a previous study reported that emotional dysregulation also mediates the effect of SSS on depressive symptoms, but in that study the direct effect of SSS was also significant (Zvolensky et al., 2017), indicating a partial mediating effect of emotional dysregulation in their model (Baron and Kenny, 1986). Further studies on various factors that mediate the effect of SSS on depressive symptoms will be required in the future.

The poor quality of parenting in childhood, which is evaluated by the PBI, is a risk factor for the onset of major depression in adulthood (Parker et al., 1995). Recently, we reported that the poor quality of parenting in childhood increased depressive symptoms in non-clinical adult volunteers, and that its effect was mediated by neuroticism (Ono et al., 2017). On the other hand, to our knowledge, there have been no reports regarding the association between the quality of parenting in childhood and SSS/OSS. Our present study first showed that SSS in adulthood significantly correlates with the quality of parenting in childhood. Psychological abuse in childhood was reportedly correlated with OSS in non-clinical adult volunteers (Sheikh et al., 2016), which is almost consistent with the result of our present study. As there is a long time interval between the quality of parenting in childhood and depressive symptoms in adulthood, some factors must mediate the link between two factors. We hypothesized that SSS is a mediator of the effect of the quality of parenting in childhood on depressive symptoms in adulthood, and tested this hypothesis in the present study. Our SEM results clarified that although SSS alone did not mediate the effects of the quality of parenting in childhood on depressive symptoms in adulthood, interestingly, the combination of SSS and self-esteem did. In short, these findings suggest that the mediating effects of SSS cannot be exerted by SSS alone, but the mediating effect of SSS for the quality of parenting requires the involvement of self-esteem.

There are some limitations to this study. Firstly, as we used a retrospective questionnaire for the analysis of the quality of parenting in childhood, recall bias and current psychiatric status may affect the evaluation. Secondly, this study used a cross-sectional design, rather than a prospective design. Therefore, it is necessary to confirm the mediating effects of SSS and self-esteem by long-term prospective studies that follow subjects in whom the quality of parenting was studied in childhood. Thirdly, as we did not evaluate OSS, we could not compare the effects of SSS with those of OSS. Fourthly, the mean PHQ-9 summary score was low at 3.3, which is in the range of 0–4, indicating no depressive symptoms (Kroenke et al., 2001). Finally, since the subjects of this study were non-clinical self-selected adult volunteers, including many healthy subjects, it may not be possible to generalize our results to patients with MDD.

In conclusion, this study showed that the quality of parenting in

childhood affects depressive symptoms of non-clinical self-selected adult volunteers indirectly through subjective social status and self-esteem. It is presumed from this study that receiving good care in childhood increases subjective social status and self-esteem of individuals and reduces depressive symptoms, leading to the prevention of mental illness or better mental health. The results of this study may contribute to the elucidation of the psychological mechanism of SSS, which has recently been drawing attention regarding the onset of mental illness.

### Conflict of interest

Jiro Masuya has received personal compensation from Otsuka Pharmaceutical, Eli Lilly, Astellas, and Meiji Yasuda Mental Health Foundation and grants from Pfizer.

Masahiko Ichiki has 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.

Ichiro Kusumi has received honoraria from Astellas, Chugai Pharmaceutical, Daiichi Sankyo, Dainippon Sumitomo Pharma, Eisai, Eli Lilly, Janssen Pharmaceutical, Kyowa Hakko Kirin, Meiji Seika Pharma, MSD, Nippon Chemiphar, Novartis Pharma, Ono Pharmaceutical, Otsuka Pharmaceutical, Pfizer, Tanabe Mitsubishi Pharma, Shionogi and Yoshitomyakuin, and has received research/grant support from AbbVie GK, Asahi Kasei Pharma, Astellas, Boehringer Ingelheim, Chugai Pharmaceutical, Daiichi Sankyo, Dainippon Sumitomo Pharma, Eisai, Eli Lilly, GlaxoSmithKline, Kyowa Hakko Kirin, Meiji Seika Pharma, MSD, Novartis Pharma, Ono Pharmaceutical, Otsuka Pharmaceutical, Pfizer, Takeda Pharmaceutical, Tanabe Mitsubishi Pharma, Shionogi and Yoshitomyakuin, and is a member of the advisory board of Dainippon Sumitomo Pharma and Tanabe Mitsubishi Pharma.

Takeshi Inoue has received personal fees from GlaxoSmithKline, Mochida Pharmaceutical, Asahi Kasei Pharma, and Shionogi; grants from Astellas; and grants and personal fees from Otsuka Pharmaceutical, Dainippon Sumitomo Pharma, Eli Lilly, Eisai, Mitsubishi Tanabe Pharma, Pfizer, AbbVie GK, MSD, Yoshitomyakuin, Takeda Pharmaceutical, and Meiji Seika Pharma; and is a member of the advisory boards of GlaxoSmithKline, Pfizer, Eli Lilly, Mochida Pharmaceutical and Mitsubishi Tanabe Pharma.

The other authors declare that they have no actual or potential conflict of interest.

### Contributors

T.H. and T.I. designed the study and wrote the protocol. T.H. collected and analyzed data. All authors checked the protocol and discussion and contributed to and have approved the final manuscript.

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