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The NVP QOL Questionnaire: Psychometric properties of the self-report measure of health-related quality of life for nausea and vomiting during pregnancy

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Abstract

Aim: The Nausea and Vomiting of Pregnancy Quality of Life (NVP QOL) Questionnaire is a self-report measure of health-related QOL for nausea and vomiting during pregnancy. This study determines the best fitting factor structure for the NVP QOL Questionnaire and explores its measurement invariance in terms of observation time and parity.

Methods: A test–retest study of pregnant women was conducted at Gestational Weeks (GWs) 10–13 (T1: $N = 381$) and 1 week later (T2: $n = 128$) at one hospital and five clinics with the NVP QOL and the Pregnancy-Unique Quantification of Emesis and Nausea (PUQE). Exploratory and confirmatory factor analyses were performed to compare different factor structure models and evaluate measurement invariance of the best fitting model between two time points and between primiparas and multiparas. Concurrent validity of the NVP QOL was clarified by correlations with the PUQE, Sheehan Disability Scale, and other scales.

Results: The one-factor model had the best fit. This factor structure model was acceptable up to the factor invariance level for two time points and up to the factor mean level for primiparas versus multiparas. Correlations between NVP QOL, PUQE, and Sheehan Disability Scale scores were strong. Women with higher NVP QOL scores were more likely to lose weight, have lower daily fluid intake, have reduced fluid and food intake since pregnancy began, and receive outpatient or inpatient treatment.

Conclusion: The one-factor structure and measurement invariance of the NVP QOL at different times and parities were demonstrated, suggesting that the NVP QOL can be used to evaluate primiparas and multiparas in a longitudinal study.

KEYWORDS
nausea, pregnancy, psychometrics, vomiting

INTRODUCTION

Research shows that 33–83% of pregnant women experience nausea and vomiting of pregnancy (NVP).[1–4] Other than nausea and vomiting, NVP also leads to loss of appetite and weight gain, affecting activities of daily living and sleep.[5] NVP is called hyperemesis gravidarum (HG) when it is accompanied by dehydration, ketonuria, and more than 5% body weight loss.[6] A majority of pregnant women report negative psychosocial changes due to HG.[7,8] NVP/HG is preceded by psychiatric disorders.[6,9,10] Depression and anxiety scores are higher among those women with NVP/HG than those without NVP/HG.[7,11–13] HG is often followed by postnatal depression,[14] postdelivery traumatic stress,[15,16] motion sickness, and muscle weakness; infants experience irritability, severe colic, and growth restriction.[16]

Despite the importance of the quality of life (QOL) in pregnant women, little progress in the treatment and care of women with NVP has occurred. This might be due to the paucity of assessment tools that are reliable and valid. The availability of such assessment tools is a *sine qua non* for treatment research. For example, Rhodes et al.'s[17] Index of Nausea and Vomiting (INV) was originally developed for patients with cancer after chemotherapy but it was later used as a measure of NVP. The INV was modified to the Pregnancy-Unique Quantification of Emesis and Nausea (PUQE),[18] which can be used to assess nausea and vomiting experienced during the last 12 h. The PUQE and the modified PUQE (measuring NVP in the last 24 h) are brief and only measure nausea and vomiting. Considering that NVP also results in undesirable effects on the QOL of women, Magee et al.[19] developed the Nausea and Vomiting of Pregnancy Quality of Life (NVP QOL) Questionnaire. The NVP QOL is a self-report measure consisting of 30 items in four domains: physical symptoms and aggravating factors, fatigue, emotions, and social limitations. NVP QOL scores are associated with the physical and mental QOL scores of the 12-item Short-Form Health Survey (SF-12), Version 1.[20] The NVP QOL has been translated into French [21] and Chinese.[22]

Identification of the factor structure of this measure and evaluation of its configural, measurement, and structural invariances are needed. A few studies reported that the NVP QOL has a four-factor structure.[19,23] However, these studies involved only exploratory factor analysis (EFA), without considering the degree to which the model fitted the data. There are several statistical issues that should be considered before reaching conclusions about the robustness of the factor structure for a measure. First, confirmation of the factor structure inherently requires consideration of cross-validation.[24,25] Second, when the factor structure of the concept is known, it is essential to consider whether the factor structure is the same in different populations and at different times in the same population, which is defined as measurement invariance.[26–28] To confirm measurement invariance, it is necessary to use confirmatory factor analysis (CFA) multiple group structure equation modeling, assuming constraints such as whether the factor loadings of each observed variable are the same between groups.

Concurrent validity and construct validity are other important psychometric properties of a measurement. If the measure works as intended, it should be fairly well correlated with other similar measures (concurrent validity) and other variables that are theoretically linked with it (construct validity).

This study aimed to identify the best fitting factor structure for the NVP QOL among a population of Japanese pregnant women. The study also evaluated measurement invariance across two observation time points and between primiparas and multiparas. Finally, we compared NVP QOL scores with measures of other experiences that were likely to occur among women with NVP.

METHODS

Study procedures and participants

Approximately 1500 pregnant women at GWs 10–13 were asked to take part in a longitudinal study in the antenatal department of a general hospital and five private clinics in Tokyo metropolitan area and Kagoshima Prefecture in Japan from January 2017 to May 2019 (Time 1: T1). Exclusion criteria were: (a) lack of fluency in Japanese, (b) age under 20 years, (c) history of an eating disorder, (d) symptoms of vaginal bleeding or abdominal pain, (e) history of subchorionic hematoma, and (f) recurrent miscarriages. A total of 381 pregnant women (approximately 25%) participated during T1.

A set of two questionnaires was distributed to participants from the six participating medical institutions. Each participant was requested to answer and submit the T1 questionnaire at that time of consent and the Time 2 (T2) questionnaire 1 week later. Of the 381 women, 128 (34%) women returned the T2 questionnaire. Test and retest responses were matched by a predetermined number on the questionnaire.

There seems to be no consensus regarding the number of required participants for CFA. We think that at least 100 participants are required for CFA.

Measurements

NVP QOL

The NVP QOL[19] is a self-report measure with 30 items to evaluate NVP and related QOL in the previous week with a 7-point Likert scale (1 = *none of the time* to 7 = *all of the time*). Of note, Item 20 is scored in reverse. The NVP QOL has four domains: physical symptoms and aggravating factors, fatigue, emotions, and social limitations. This scale was translated into Japanese by one author (M. M.) with the permission of the original author. Another author (T. K.), a British qualified psychiatrist, checked the feasibility of the wording. The Japanese version was retranslated back into English by a native English translator who was unaware of the original English text. All of the back-translated items were confirmed by the original author.

PUQE-24

We used the Japanese version[29] of the 24-item Pregnancy-Unique Quantification of Emesis and Nausea (PUQE-24),[30] which is a self-reported measure of nausea and vomiting in the last 24 h. The PUQE-24 consists of three items (nausea, vomiting, and retching) with a 5-point Likert scale. Based on the INV,[17] the original PUQE[18] measured the daily number of vomiting episodes, duration of nausea in hours per day, and number of retching episodes per 12 h. Ebrahimi et al.[30] modified the scale to measure symptoms over the last 24 h. The PUQE is widely used in many countries.[21,31–34]

Sheehan Disability Scale

We used the Japanese version[35] of the Sheehan Disability Scale (SDS).[36] The SDS is a self-reported measure of disabilities in domains of (a) work and school work, (b) social and leisure activities, and (c) family life and home responsibility. Each item is rated from 0 to 10 (0 = *not at all* to 10 = *extremely*). The SDS's psychometric properties were reported previously.[37]

Other emesis-related measures: We created five ad hoc items to assess emesis-related conditions: (a) severity of nausea and vomiting during the past week ("How severe was your nausea or vomiting in the past week?") with a 7-point scale (1 = *not at all*, 2 = *very mild*, 3 = *mild*, 4 = *moderate*, 5 = *slightly severe*, 6 = *severe*, and 7 = *very severe*); (b) weight loss in kilograms compared to prepregnancy; (c) daily fluid intake ("How much fluid did you drink each day in the past week?") measured in milliliters; (d) changes in fluid or food intake ("How does your fluid or food intake in the past week compare with your prepregnancy intake?") with a 7-point scale (1 = *extremely reduced*, 2 = *reduced*, 3 = *slightly reduced*, 4 = *unchanged*, 5 = *slightly increased*, 6 = *increased*, and 7 = *extremely increased*); and (e) outpatient visit or inpatient admission for HG (1 = *neither*, 2 = *outpatient visit*, and 3 = *inpatient admission*).

Data analysis

To cross-validate the factor structure, the entire sample ($N = 381$) was divided randomly into two parts: one ($n = 183$) for EFA and another ($n = 198$) for CFA. For the EFA group, Little's Missing Completely at Random (MCAR) test was used to examine the characteristics of the missing values. The Kaiser–Meyer–Olkin (KMO) index and Bartlett's sphericity test were used to perform a factorability check.[38] A series of EFAs were conducted using the maximum-likelihood method with Promax rotation from a one-factor structure and then in models with more factors. The factor structure models derived from EFAs were compared using the second half of samples in terms of fitness with the data via CFAs. The fit of these models with the data was expressed with three indices: χ^2, comparative fit index (CFI), and root-mean-square error of approximation (RMSEA). A good fit was defined as $\chi^2/df < 2$, CFI > 0.97, and RMSEA < 0.05. An acceptable fit was defined as $\chi^2/df < 3$, CFI > 0.95, and RMSEA < 0.08.[38,39] The Akaike information criterion (AIC)[40] was also used to assess fit. A model with lower AIC was considered better than a model with higher AIC. The models were compared, beginning with the one-factor model. A model with more factors was only accepted if it were statistically superior. Otherwise, the model with fewer factors was prioritized.

As described later, the final factor model did not fit with the data sufficiently. Thus, we created item parcels by aggregating scores of several items. Item parceling was used for the following reasons. First, 30 items per factor are too many. Second, there were highly correlated errors. Third, it was difficult to consider a 7-point Likert scale as continuous. A factorial algorithm[41] was used for item parceling. Each parcel sequentially took up items with the highest and the lowest factor loadings.[42] In this study, seven parcels were built from 30 items. We examined the mean, standard deviation (SD), skewness, and kurtosis of all NVP QOL item parcels. The factor structure model derived from EFAs was compared with the second half of samples using CFAs.

After identifying the best fitting model, we examined measurement invariance across two types of occasions (T1 vs. T2) and between primiparas versus multiparas at T1. We used multiple-group structural equation modeling. We defined invariance as either (a) a nonsignificant increase in χ^2 for *df* of difference; (b) decrease in CFI of <0.01; or (c) increase in RMSEA of <0.01.[43,44]

Finally, we correlated NVP QOL scores with PUQE-24 scores, SDS scores, severity of nausea and vomiting, weight loss, daily fluid intake, changes in fluid or food intake, and outpatient visit or inpatient admission for HG.

RESULTS

Sample characteristics

The response rate for T1 and T2 was 25% and 34%, respectively. Of 381 pregnant women responding at T1, mean (SD) age was 31.9 (4.9) years. Their partner's mean age (SD) was 33.5 (5.5) years. Most were married (95%). Of the respondents, 44% were primiparas and 55% were multiparas. Mean (SD) weight before pregnancy was 52.7 (8.3) kg. Mean (SD) height was 158 (5.3) cm. Of the total sample, 56% were employed, 34% were housewives, and 10% were on parental leave.

Factor analyses

We used the first half of samples to conduct EFA. Almost all NVP QOL items showed no excessive skewness or kurtosis (Table 1). Little's MCAR test showed that the data were missing completely at random: χ^2 (*df*) = 886.911 (880) ($p = 0.429$). The data were found to be factorable: KMO = 0.955; Bartlett's sphericity χ^2 (435) = 5585.557 ($p < 0.001$). The Eigenvalue was extremely high for the first factor

TABLE 1 Mean, standard deviation, skewness and kurtosis of the NVP QOL item parcels (n = 183)

Parcels	Item contents	*n*	Mean (SD)	Skewness	Kurtosis
1	Items 12, 18, 20, and 30	176	15.1 (5.2)	0.20	−0.27
	12: Frustrated	178	3.2 (1.7)	0.45	−0.66
	18: Tired	181	3.6 (1.8)	0.24	−0.92
	20: Reassured that your symptoms are part of normal pregnancy	183	4.5 (1.8)	−0.42	−0.80
	30: Difficulty preparing or cooking meals	183	3.9 (2.1)	0.09	−1.25
2	Items 8, 9, 21, and 24	183	14.9 (6.1)	−0.18	−0.66
	8: Worn-out, lack of energy	183	3.4 (1.8)	0.33	−0.79
	9: Poor appetite	183	3.6 (1.8)	0.17	−0.87
	21: Less interested in sex	183	4.4 (2.1)	−0.32	−1.22
	24: Accomplished less than you would like	183	3.6 (1.8)	0.31	−0.87
3	Items 2, 6, 14, and 23	183	12.3 (5.6)	0.32	−0.64
	2: Vomiting	183	1.9 (1.4)	1.50	1.35
	6: Difficult or took extra effort to perform, and/or limited in types of work/other activities	183	3.5 (1.9)	0.34	−1.05
	14: Rely on your partner to do things that you would normally do for family	183	3.8 (1.9)	0.04	−1.09
	23: Emotional	183	3.1 (1.7)	0.57	−0.55
4	Items 1, 10, 27, and 28	182	12.4 (5.8)	0.34	−0.76
	1: Nausea	183	3.8 (1.7)	−0.01	−0.72
	10: Difficulty maintaining your normal social activities with family, friends, neighbors, or social groups	183	2.9 (1.7)	0.67	−0.37
	27: Everything is an effort	182	2.9 (1.8)	0.70	−0.55
	28: Can't enjoy your pregnancy	183	2.8 (1.6)	0.62	−0.60
5	Items 4, 7, 16, and 29	183	13.6 (5.5)	0.09	−0.75
	4: Sick to your stomach	183	4.1 (1.7)	−0.01	−0.83
	7: Downhearted, blue	183	3.1 (1.8)	0.50	−0.62
	16: Difficulty looking after home	183	3.6 (1.8)	0.19	−0.88
	20: Reassured that your symptoms are part of normal pregnancy	183	4.5 (1.8)	−0.42	−0.80
6	Items 3, 5, 19, and 25	183	12.8 (5.6)	0.22	−0.53
	3: Dry-heaves	183	2.8 (1.7)	0.45	−0.80
	5: Took longer to get things done than usual	183	3.6 (1.7)	0.03	−0.87
	19: Not eaten for longer than you would like	183	3.0 (1.7)	0.57	−0.59
	25: Cut down on amount of time you spent at work/other activities	183	3.3 (1.8)	0.43	−0.85

Parcels	Item contents	*n*	Mean (SD)	Skewness	Kurtosis
7	Items 11, 13, 15, 17, 22, and 26	181	20.3 (9.3)	0.20	−0.89
	11: Symptoms worse in evening	183	3.8 (1.9)	0.12	−1.14
	13: Exhausted	182	3.1 (1.8)	0.53	−0.66
	15: Fed up with being sick	183	2.7 (2.0)	0.92	−0.35
	17: Difficulty shopping for food	182	3.5 (1.9)	0.38	−0.96
	22: Fatigue	183	3.6 (1.8)	0.21	−0.97
	26: Worse when exposed to certain smells	183	3.6 (1.9)	0.27	−1.04

Abbreviation: NVP QOL, Nausea and Vomiting of Pregnancy Quality of Life Questionnaire.

(18.221) when compared with the subsequent factors: second factor, 1.587; third factor, 1.252; and fourth factor, 0.997. We analyzed models with 1–4 factors (Table 2). We compared the factor structure of the models with CFA using the second half of samples. Compared with the one-factor model ($\chi^2 = 1383.775$, $df = 405$), the two-factor model ($\chi^2 = 1286.042$, $df = 404$) had better fit ($\Delta\chi^2$ (df) = 97.773, $p < 0.001$) but differences in CFI (0.841 vs. 0.857) and RMSEA (0.111 vs. 0.105) were very small. Thus, we considered the one-factor model to be acceptable for the sake of parsimony. The absolute fit with the data was less than acceptable for both the one-factor (CFI = 0.841) and two-factor (CFI = 0.857) models.

Items parceling

Seven item parcels were created by combining NVP QOL items (Table 1). The NVP QOL parcels had good skewness at T1. All items had skewness <2.0 and kurtosis <4.0. We used the first half of samples to perform EFA of the NVP QOL item parcels (Table 3). All item parcels had factor loadings >0.3 in the one-factor model. In the two-factor model, six-item parcels had factor loadings >0.3 for the first factor. Only two-item parcels had higher factor loadings for the second factor than for the first factor. These two factor models were compared in terms of goodness of fit with the data using the second half of samples. The one-factor model had excellent fit: $\chi^2/df = 2.282$, CFI = 0.992, and RMSEA = 0.08. The two-factor model did not have a statistically better fit with the data than the one-factor model: $\Delta\chi^2$ (df) = 3.019 (1) NS. Therefore, the one-factor model was the best factor structure model for the NVP QOL scale.

Measurement invariance

After identifying the one-factor, seven-parcel model as the best model, we examined measurement invariance across the observation times, T1 and T2. Measurement invariance was acceptable based on configural up to factor variance levels (Table 4). Similarly, the comparison of primiparas and multiparas showed measurement invariance up to the factor variance level. Therefore, the factor structure of the NVP QOL had invariance over the observation period as well as across parity. Regarding factor means, the factor mean at T2 was significantly lower than that at T1 (−1.409, $p < 0.01$). Factor means did not differ between primiparas and multiparas.

Concurrent and construct validity

NVP QOL scores were correlated significantly with PUQE ($r = 0.82$, $p < 0.001$) and SDS ($r = 0.69$, $p < 0.001$) scores. They were also correlated with self-reports of nausea ($r = 0.75$, $p < 0.001$) and vomiting ($r = 0.50$, $p < 0.001$), weight loss ($r = 0.39$, $p < 0.001$), daily fluid intake ($r = -0.15$, $p < 0.01$), changes in fluid intake ($r = -0.27$, $p < 0.001$), changes in food intake ($r = -0.49$, $p < 0.001$), and outpatient or inpatient treatment for HG ($r = 0.16$, $p < 0.01$). The NVP QOL had good internal consistency (Cronbach's $\alpha = 0.97$) at T1 and acceptable test–retest reliability (intraclass correlation coefficient = 0.70; 95% confidence interval, 0.47–0.82).

DISCUSSION

This study found that the NVP QOL has a one-factor model. Although other studies demonstrated a four-factor structure, these studies did not validate the model using CFAs.[19,20,23] For example, Magee et al.[19] referred to the scree plot and noted that the solution contained as many as four factors. However, it is well known that the scree plot often suggested more factors than necessary. Thus, CFAs based on EFAs are required. Magee et al.[19] and Chung et al.[23] used principal component analysis (PCA) to conduct EFA. PCA is different from EFA; they should not be treated as equal.[45] Lacasse and Bérard[20] examined the validity of the NVP QOL using factors based on Magee et al.'s[19] factor analysis. Different populations might not have the same factor structure. EFAs and CFAs need to be performed. Some studies only investigated the internal consistency of the subscale in a cross-sectional study, without a two-time-point survey.[20,23] The fact that NVP QOL, as demonstrated in our study, has a one-factor structure indicates that there is essentially one concept of NVP QOL, which expresses a variety of phenomena, such as tiredness, lack of energy,

TABLE 2 Exploratory factor analyses of NVP QOL items

Items	One-factor	Two-factor		Three-factor			Four-factor			
	I	I	II	I	II	III	I	II	III	IV
1	**0.75**	**0.39**	**0.41**	0.15	**0.42**	**0.31**	0.06	0.27	**0.32**	**0.31**
2	**0.49**	0.22	**0.31**	−0.09	**0.44**	0.25	−0.10	**0.46**	0.24	−0.05
3	**0.63**	**0.38**	0.28	−0.14	**0.66**	0.23	−0.24	**0.47**	**0.47**	0.04
4	**0.69**	**0.45**	0.27	0.26	**0.33**	0.18	0.13	0.06	**0.36**	**0.37**
5	**0.87**	**0.49**	**0.43**	**0.68**	−0.01	0.28	**0.66**	0.04	0.03	**0.33**
6	**0.88**	**0.51**	0.42	**0.91**	−0.22	0.27	**0.92**	0.05	−0.14	0.16
7	**0.86**	**0.94**	−0.07	**0.84**	0.17	−0.14	**0.69**	−0.01	**0.36**	−0.18
8	**0.87**	**0.97**	−0.09	**0.87**	0.18	−0.16	**0.69**	−0.15	**0.41**	−0.01
9	**0.79**	**0.46**	**0.37**	**0.46**	0.17	0.25	**0.40**	0.08	0.18	**0.34**
10	**0.84**	**0.60**	0.27	**0.89**	−0.14	0.14	**0.86**	0.08	−0.03	−0.04
11	**0.69**	**0.41**	**0.33**	0.03	**0.53**	0.25	−0.08	**0.35**	**0.41**	0.18
12	**0.81**	**0.94**	−0.11	**0.41**	**0.61**	−0.15	0.18	0.14	**0.69**	−0.14
13	**0.86**	**1.09**	−0.23	**0.62**	**0.53**	−0.26	**0.37**	−0.05	**0.70**	−0.10
14	**0.84**	0.25	**0.67**	**0.31**	0.19	**0.49**	**0.34**	**0.55**	−0.00	0.07
15	**0.73**	**0.57**	0.20	0.23	**0.47**	0.12	0.14	**0.40**	**0.38**	−0.15
16	**0.87**	0.27	**0.68**	**0.33**	0.20	**0.49**	**0.36**	**0.63**	−0.01	−0.03
17	**0.85**	0.17	**0.78**	0.27	0.17	**0.58**	**0.34**	**0.77**	−0.12	−0.07
18	**0.89**	**0.95**	−0.04	**0.55**	**0.51**	−0.11	**0.33**	0.08	**0.61**	−0.04
19	**0.70**	0.26	**0.50**	0.12	**0.33**	**0.37**	0.08	**0.40**	0.18	0.20
20	−0.14	**0.31**	−**0.49**	0.12	0.07	−**0.40**	0.08	−0.01	0.16	−**0.62**
21	**0.54**	0.27	**0.31**	0.09	**0.32**	0.22	0.01	0.17	0.26	0.27
22	**0.86**	**1.01**	−0.14	**0.44**	**0.67**	−0.20	0.17	0.03	**0.79**	−0.02
23	**0.76**	**0.85**	−0.08	**0.67**	0.25	−0.14	**0.47**	−0.04	**0.43**	−0.05
24	**0.83**	**0.67**	0.18	**0.81**	−0.01	0.06	**0.69**	−0.04	0.16	0.11
25	**0.86**	**0.64**	0.25	**0.81**	−0.03	0.12	**0.73**	0.12	0.08	−0.04
26	**0.66**	0.19	**0.53**	0.01	**0.39**	**0.41**	−0.02	**0.58**	0.17	0.04
27	**0.83**	**0.68**	0.18	**0.72**	0.08	0.07	**0.63**	0.16	0.17	−0.12
28	**0.79**	**0.68**	0.13	**0.55**	0.25	0.05	**0.45**	**0.33**	0.26	−**0.30**
29	**0.66**	0.18	**0.55**	0.01	**0.38**	**0.43**	−0.00	**0.56**	0.15	0.08
30	**0.83**	0.04	**0.89**	0.06	0.28	**0.69**	0.14	**0.88**	−0.09	0.02

Note: Factor loadings >0.3 are in bold.

Abbreviation: NVP QOL, Nausea and Vomiting of Pregnancy Quality of Life Questionnaire.

depression, and lower social functioning (e.g., inability to perform social and household activities, difficulties in interpersonal relationships, and lower social functioning).

No differences were observed in the means of latent factors between primiparous and multiparous women. However, NVP QOL scores were significantly lower at T2 than at T1. This can be interpreted to mean that NVP QOL scores improved from T1 (GWs 10–13) to T2 (1 week later). The results were predictable, as the onset of nausea and vomiting usually begins by GWs 4–6, with a peak in incidence and severity by GWs 8–12 and resolution of symptoms generally by GW 20.[5]

Concurrent validity and construct validity were shown by the correlations between NVP QOL scores and other measures of NVP (PUQE and other self-report measures). NVP QOL scores were also correlated with weight loss, less daily fluid intake, and lower fluid and food intake since pregnancy. Pregnant women with high NVP QOL scores were more likely to be treated as outpatients or inpatients. NVP QOL and PUQE scores were correlated ($r = 0.82$), which means

that 33% of the variance was not shared by the two measures. Thus, while the PUQE measures only nausea, vomiting, and retching, the NVP QOL assesses reduced QOL due to emesis. Therefore, if researchers and clinicians wish to measure emesis-induced decreases in QOL, use of the NVP QOL is recommended.

Researchers are encouraged to use the NVP QOL in studies linking emesis to a variety of mental illnesses during the perinatal period, including mood, anxiety, and stress-related disorders. Because HG is often associated with depression, it may be of interest to see whether psychotherapy for antenatal depression will lead to less nausea and vomiting. Clinicians might want to use the NVP QOL repeatedly as a measure of HG so that they can monitor the response of a pregnant woman to their care.

This study confirmed measurement invariance in T1 versus T2 and primiparous versus multiparous women. This result indicates that it is possible to compare the scores from these occasions, which might lead to studies that clarify the factors associated with and treatment for NVP.

TABLE 3 Exploratory factor analyses of NVP QOL item parcels (n = 183)

Parcels	One-factor	Two-factor	
	I	I	II
1	**0.86**	0.09	**0.84**
2	**0.91**	**0.80**	0.13
3	**0.94**	**0.77**	0.20
4	**0.93**	**0.60**	**0.36**
5	**0.96**	**0.63**	**0.36**
6	**0.94**	**0.86**	0.10
7	**0.95**	**0.42**	**0.58**

Note: Factor loadings >0.3 are in bold.

Abbreviation: NVP QOL, Nausea and Vomiting of Pregnancy Quality of Life Questionnaire.

LIMITATIONS

This study had some limitations. First, all subjects were recruited from outpatient departments. In addition, they did not undergo structured interviews in accordance with the diagnostic criteria for HG. In addition, data on urine ketones, one of the diagnostic criteria for HG, were not collected. Thus, no distinction was made between NVP and HG. Second, the sample size at T2 was small. Finally, the measurement period in this study was limited to the first trimester of pregnancy. Measurement invariance has not been confirmed in all pregnancy stages; therefore, it is necessary to explore that issue in future studies.

CONCLUSION

A one-factor model of NVP QOL was confirmed based on measurement invariance at two time points in the first trimester and between primiparous and multiparous women. The use of the NVP QOL is recommended for research or clinical practice.

TABLE 4 Measurement and Structural Invariance of the NVP QOL

	χ^2	df	χ^2/df	$\Delta\chi^2$ (df)	CFI	ΔCFI	RMSEA	ΔRMSEA	AIC	Judgement
Time 1 (n = 381) versus Time 2 (n = 128)										
Configural	80.454	28	2.873	Ref	0.990	Ref	0.061	Ref	164.454	ACCEPT
Metric	97.942	34	2.881	17.488 (6)**	0.988	0.002	0.061	0.000	169.942	ACCEPT
Scalar	124.357	41	3.033	26.415 (7)***	0.985	0.003	0.063	0.002	182.357	ACCEPT
Residual	143.486	48	3.989	19.129 (7)***	0.982	0.003	0.063	0.000	187.486	ACCEPT
Factor variance	143.676	49	2.932	0.190 (1) NS	0.983	+0.001	0.062	+0.001	185.676	ACCEPT
Primiparas (n = 167) versus multiparas (n = 210)										
Configural	76.271	28	2.724	Ref	0.988	Ref	0.068	Ref	160.271	ACCEPT
Metric	81.123	34	2.386	4.852 (6) NS	0.988	0.000	0.061	0.007	153.123	ACCEPT
Scalar	90.186	41	2.200	9.063 (7) NS	0.988	0.000	0.057	0.004	148.186	ACCEPT
Residual	100.502	48	2.094	10.316 (7) NS	0.987	0.001	0.054	0.003	144.502	ACCEPT
Factor variance	101.217	49	2.066	0.715 (1) NS	0.987	0.000	0.053	0.001	143.217	ACCEPT

Abbreviations: AIC, Akaike's information criterion; CFI, confirmatory factor analysis; NS, not significant; NVP QOL, Nausea and Vomiting of Pregnancy Quality of Life Questionnaire; RMSEA, root-mean-square error of approximation.

**p < 0.01; ***p < 0.001.

AUTHOR CONTRIBUTIONS

Conceptualization: Toshinori Kitamura. *Methodology*: Toshinori Kitamura and Mariko Minatani. *Data collection*: Toshinori Kitamura, Mariko Minatani, Ayako Hada, and Mikiyo Wakamatsu. *Statistical analysis*: Fukiko Yamada and Toshinori Kitamura. *Writing*: Fukiko Yamada, Yaeko Kataoka, and Toshinori Kitamura. *Project administration*: Toshinori Kitamura.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data set used and analyzed in the present study is available from the corresponding author upon reasonable request.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the research ethics committees of the Kitamura Institute of Mental Health Tokyo, Tokyo, Japan (No. 2015052301) and Kagoshima University (No. 170247). All participants gave written informed consent after understanding the study rationale and procedure. The authors assert that all procedures contributing to this study comply with the ethical standards of the national and institutional committees on human experimentation and with the Helsinki Declaration of 1975 as revised in 2008. All participants provided written informed consent.

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