BMJ Open

Psychometric properties of the Chinese version of WHOQOL-HIV BREF to assess quality of life among People Living with HIV/AIDS

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Psychometric properties of the Chinese version of WHOQOL-HIV BREF to assess quality of life among People Living with HIV/AIDS

Yaxin Zhu[1], Jie Liu[2], Bo Qu[1]*

[1]Department of Social Medicine, School of Public Health, China Medical University, Shenyang, Liaoning Province, P.R. China

[2]Department of Health Statistics, School of Public Health, China Medical University, Shenyang, Liaoning Province, P.R. China

* **Correspondence to:** Bo Qu, M.D., Ph.D., Department of Health Statistics, School of Public Health, China Medical University, 77 Puhe road, Shenyang North New Area, Shenyang 110122, People's Republic of China.

Tel: 86-24-31939588

Fax: 86-24-31939588

E-mail: qubo6666@163.com

1

Abstract

Objectives: This study aims to assess the psychometric properties of the Chinese version of WHOQOL-HIV BREF.

Design: Cross-sectional study

Setting: Center for Disease Control and Prevention (CDC) and infectious diseases hospitals in three Chinese provinces.

Participants: Sample of 1100 people living with HIV/AIDS (PLWHA).

Interventions: We recruited 1100 PLWHA to evaluate for QOL with the WHOQOL-HIV BREF. Of these participants, 57 were randomly selected to repeat the QOL evaluation 2 weeks later.

Main outcome measures: The reliability of the WHOQOL-HIV BREF was assessed with internal consistency and test-retest reliability. The construct, concurrent, convergent, discriminant, and known-group validity were also analyzed. And the factorial invariance across gender was assessed.

Results: The overall Cronbach's α coefficient was 0.93. Except for the spirituality domain, with an α below 0.70 (0.66), the other five domains were confirmed to have adequate internal consistency. The test-retest reliability revealed a statistically significant intraclass correlation coefficient (ICC) of 0.72–0.82 ($p < 0.001$). A confirmatory factor analysis found that the six-domain structure produced an acceptable fit to the data. The instrument showed factorial invariance across gender groups. All domains were significantly correlated with general items and SF-36 ($p < 0.01$). The correlation coefficients were >0.40 ($r = 0.40$–0.67), except for the

association between the spirituality domain and two general items (QOL: $r = 0.33$;

health status: $r = 0.36$). Subjects with lower CD4 counts had lower scores for all

domains ($p < 0.05$). The symptomatic participants had significantly lower scores than

asymptomatic participants for the physical, psychological, and independence domains

($p < 0.05$).

Conclusions: The WHOQOL-HIV BREF revealed good psychometric characteristics

among Chinese PLWHA. These findings offer promising support for the use of the

WHOQOL-HIV BREF as a measure of QOL among Chinese PLWHA, and in

cross-cultural comparative studies on QOL.

Strengths and limitations of this study

1. This study will provide reference for better promoting quality of life (QOL)

evaluation in Chinese people living with HIV/AIDS (PLWHA).

2. In our study, the psychometric properties were analyzed comprehensively.

3. The study sample was recruited from three provinces covering the geographic

diversity of northern, central, and southern China.

4. A longitudinal design might further measure the sensitivity of this instrument to

changes in the HIV-related indicators such as CD4 count and HIV stage

Introduction

The number of people living with HIV/AIDS (PLWHA) in China has continued to increase from 351,709 in 2011[1] to 577,423 in 2015.[2] According to the national data, as of February 2016, China had 591,632 PLWHA.[3] Although the number of PLWHA is rising, the fatality rate for AIDS has decreased gradually since 2011 as the result of increasing availability of highly active antiretroviral therapy (HAART).[1] The national epidemic data showed that the number of PLWHA who were currently receiving HAART increased from 295,358 in 2014[1] to 382,139 in 2015.[2] The expanded use of HAART has increased the life expectancy of PLWHA.[4,5]

Since the advent of HAART, AIDS has transformed from an acute fatal infection into a manageable chronic disease.[4,6] The evaluation of quality of life (QOL) has been demonstrated to be crucial in chronic disease treatment over the past decades.[7,8] Moreover, because AIDS is an incurable disease, PLWHA will continue to suffer from the disease.[7] Thus, QOL assessment has recently become an essential element AIDS care,[7,9–12] and improving the QOL among PLWHA has become a priority.[13]

In recent years, there has been much research on AIDS-related QOL.[12-17] To better understand and evaluate the QOL in PLWHA, a reliable and valid measurement tool for QOL is important.[7,11] There have been several instruments applied in the QOL assessment of PLWHA, such as EQ-5D,[15] SF-36,[17] WHOQOL-HIV BREF,[16] MOS-HIV,[14] AIDS-HAQ,[18] and FAHI.[19] Compared with generic questionnaires, AIDS-specific questionnaires have greater relevance and sensitivity.[20] Reychler also suggested that disease-specific tools for assessing QOL are of particular relevance for

4

HIV-infected patients.[7] Some instruments have been developed within a single culture, particularly Western culture. Consequently, versions that have been translated into a different language often present lower equality of semantic and concept, which was demonstrated by poorer psychometric characteristics.[13,21,22] Furthermore, previous studies suggested that a cross-culturally valid QOL measure may be important for assessing health delivery in various cultural conditions.[6,20]

In 2003, WHO developed the WHOQOL-HIV, with 120 items (100 generic items and 20 HIV-related items).[20,23] The WHOQOL-HIV is a multi-dimensional instrument developed by multi-national collaboration. Furthermore, the instrument has been proven through field test to be promising for QOL assessment in different cultural contexts.[24] The Chinese version of WHOQOL-HIV was developed by the research team from Sun Yat-sen University and China Academy of Chinese Medical Sciences.[25,26]

WHOQOL-HIV BREF is the short version of the WHOQOL-HIV, including 31 items covering six domains.[9] And it was translated into different languages and has been proven reliable and valid.[9,16,27] Although a few studies have applied this instrument among Chinese PLWHA,[28,29] its psychometric properties have not been fully assessed. This study was designed to assess the psychometric properties of WHOQOL-HIV BREF among Chinese PLWHA. These findings may be of great importance for better understanding their QOL.

Materials and Methods

Ethics statement

Ethical protocol was obtained from the Bioethics Advisory Commission of China Medical University. The investigators informed all participants about the purpose of the study and assured them before research began that their privacy would be protected. All of the subjects provided written informed consent and voluntarily completed self-administered questionnaires.

Study population and procedures

A convenience sample was recruited from five cities (Shenyang, Dalian, Dandong, Zhengzhou, Ningbo) covering the geographic diversity of northern, central, and southern China. Shenyang, Dalian, and Dandong are three cities in Liaoning province, which is situated in the northeast region of China. Zhengzhou is the capital of Henan province, in the central region of China. Ningbo is a city in Zhejiang province, which is in the southern region of China. Inclusion criteria were that participants were 18 years or older, infected with HIV, and without cognitive impairment. A total of 1201 PLWHA were recruited from local Center for Disease Control and Prevention (CDC) and infectious diseases hospitals between February 2015 and January 2016. To ensure the quality of the questionnaire, after completing the questionnaires, specially trained investigators inspected the questionnaires, identified the questionnaires that were filled out with non-standard and ambiguous answers. All of the subjects received a self-reported questionnaire and were compensated with 50 Chinese Yuan after completing the questionnaire. If >20% of one questionnaire were missing, the questionnaire was regarded as invalid. Questionnaires with valid responses were collected from a total of 1100 participants, and the valid response rate was 91.6%.

6

MM Shoukri et al. suggested that sample size for the design of test-retest reliability

study required to estimate ICC of 0.8 with a 95% CI having width of 0.2 (i.e. the

value of ICC is between 0.7 and 0.9) should be 52.[30] To examine the test-retest

reliability, 57 participants were randomly selected to complete the QOL evaluation

again 2 weeks later.

Questionnaire

The survey questionnaire comprised four sections including socio-demographic

information, HIV-related characteristics, WHOQOL-HIV BREF, and SF-36. The

socio-demographic information included age, gender, work status, and so on.

HIV-related characteristics consisted of HIV stage, CD4 cell counts, mode of HIV

transmission, and time since diagnosis. As categorized by the clinically meaningful

cut-off points,[31] CD4 cell count was stratified into three groups. HIV stage was

divided into two groups: HIV-asymptomatic and HIV-symptomatic.[13,21,32]

WHOQOL-HIV BREF consists of 31 items rated on a five-point Likert scale.

Among the 31 items, 29 domain-specific items are used to measure individual QOL

across six domains. The other two items are used to measure perspective of general

QOL and health status. The domain scores were calculated by multiplying the mean of

all items within the domain by 4. All domain scores range from 4 to 20. Higher scores

in each domain indicate higher QOL for that domain. Hao and He translated

WHOQOL-HIV BREF into Chinese according to the method proposed by WHO.[25,26]

SF-36 is a widely-used QOL evaluation tool in the world.[33] And this generic

measurement tool has proven to be reliable and validity for assessing of QOL of

7

PLWHA.[34,35] SF-36 includes 36 items covering 8 domains, and the domain scores form two summary scores.[7] They are the physical component summary (PCS) and the mental component summary (MCS) scores, which range from 0 to 100.[36,37] Higher scores indicating a better QOL. The reliability of this instrument in our study was satisfactory, with the alpha equaling to 0.93.

Statistical analysis

The missing data were replaced by median. The mean, standard deviation (SD), skeweness, kurtosis, floor effects, and ceiling effects of each item and domain were computed. Floor or ceiling effects were significant if the percentage of subjects having the lowest or the highest score was >20%.[27,38] Cronbach's α coefficient of ≥0.70 was considered acceptable internal consistency reliability. Intraclass correlation coefficient (ICC) was applied for test-retest reliability, with ICC ≥ 0.70 indicating good test-retest reliability.[39]

To test the construct validity, confirmatory factor analysis (CFA) was used.[40] Goodness-of-fit was evaluated using the indexes including χ^2, root mean square error of approximation (RMSEA), comparative fit index (CFI), and adjusted goodness-of-fit index (AGFI). A RMSEA value <0.08 and a CFI value >0.90 indicated a good fit.[40] For AGFI, a value of >0.85 was considered adequate model fit.[40] A multiple-group CFA analysis was conducted to investigate whether the WHOQOL-HIV BREF is measuring same constructs across gender groups. First, we assessed for configural invariance. The next step involved assessing for metric invariance by examining if the factor loadings were the same across gender groups.

8

Changes in CFI (ΔCFI ≤0.01) was used to demonstrate factorial invariance across groups.[13,41]

Regarding concurrent validity, all domains were correlated with two general items (QOL and health status) and SF-36.[7,25] The scale's convergent and discriminant validity were tested by calculating item-domain Pearson's correlations. A correlation coefficient of >0.4 for items with their respective domain was considered to be satisfactory.[7,27] Items revealing higher correlations with the respective domain score than with other domains indicated good discriminant validity.[42]

Known-group validity was used to test how well the WHOQOL-HIV BREF discriminated among the subgroups of participants with regard to CD4 count and HIV stage. Multivariate analysis of variance (MNOVA) was conducted to analysis the known-group validity. Post hoc tests were conducted to examine significant differences in domain scores among the three CD4 groups. It was hypothesized that HIV-symptomatic participants and PLWHA with lower CD4 counts would have significantly lower QOL domain scores. Values of $p < 0.05$ were considered to be statistically significant. SPSS 19.0 and LISREL 8.5 software for Windows was used.

Results

Basic characteristics of the study sample

The mean age of the 1100 participants was 39.62 years, with a SD of 12.73. Most of the participants were male (965, 87.7%). Of the 1100 participants, 713 (64.8%) were infected with HIV through male homosexual sex. 691 (62.8%) were asymptomatic. The time since diagnosis was 3.91 years (SD = 2.85). The

9

socio-demographic and HIV-related characteristics are shown in Table 1.

Table 1. Socio-demographic and HIV-related characteristics of the sample (*N* = 1100).

Characteristic	Number	Percentage
Gender		
Male	965	87.7%
Female	135	12.3%
Work status		
Employed full-time	643	58.4%
Employed part-time	420	38.2%
Unemployed	37	3.4%
Marital status		
Single	450	40.9%
Married	443	40.3%
Divorced/Widowed	207	18.8%
Education level		
Primary school or lower	138	12.5%
Junior high school	331	30.1%
Senior high school	235	21.4%
Junior college	184	16.7%
College or above	212	19.3%
Residence		
Shenyang	193	17.6%
Dalian	205	18.6%
Dandong	123	11.2%
Zhengzhou	381	34.6%
Ningbo	198	18.0%
Monthly income (Yuan)		
<1000	222	20.2%
1001–2000	256	23.3%
2001–3000	314	28.5%
≥3001	308	28.0%
HIV stage		
Symptomatic	409	37.2%
Asymptomatic	691	62.8%
CD4 count (cells/mm^3)		
<200	99	9.0%
200–499	642	58.4%
≥500	359	32.6%
Mode of HIV transmission		

Male homosexual sex	713	64.8%
Heterosexual sex	210	19.1%
Drug abuse	11	1.0%
Blood product	112	10.2%
Unknown	54	4.9%

Score distributions

The descriptive statistics of each item and domain are displayed in Table 2. The

skewness and kurtosis coefficients of all items and domains ranged from −1.00 to

1.00, which were acceptable. No significant floor or ceiling effects were found in the

six domains. However, the item measuring pain and discomfort showed a significant

ceiling effect (35.9%), and floor effects were detected in the items measuring social

inclusion (22.4%) and financial resources (24.2%). Across domains, the physical

domain had the highest score (13.76 ± 2.94), and the environment domain score was

the lowest (12.05 ± 2.88).

11

Table 2. Descriptive statistics of the WHOQOL-HIV BREF (N = 1100).

Domain or item	Mean ± SD	Skewness	Kurtosis	Floor (%)	Ceiling (%)
General QOL	3.27 ± 0.92	−0.18	0.5	5.0	9.8
General health status	3.10 ± 0.94	−0.09	−0.09	5.2	6.6
Physical	13.76 ± 2.94	−0.19	−0.25	0.1	1.5
Pain and discomfort	4.01 ± 0.99	−0.98	0.46	1.8	35.9
Symptoms of PLWHA	3.48 ± 1.08	−0.49	−0.64	3.9	15.3
Energy and fatigue	3.19 ± 1.19	−0.02	−0.91	7.9	17.6
Sleep and rest	3.08 ± 1.04	−0.19	−0.33	8.7	8.3
Psychological	12.16 ± 2.81	0.26	−0.16	0.1	0.8
Positive feelings	2.83 ± 1.09	0.04	−0.71	12.5	5.9
Cognition	2.90 ± 1.00	0.01	−0.47	8.3	5.0
Body image and appearance	3.07 ± 1.11	0.10	−0.50	8.1	13.3
Self-esteem	3.17 ± 0.98	−0.25	−0.18	5.8	7.4
Negative feelings	3.24 ± 0.99	0.03	−0.25	4.0	12.5
Independence	13.19 ±2.82	−0.13	0.17	0.2	1.6
Dependence on medication/treatment	3.02 ± 1.12	0.07	−0.78	8.3	10.7
Mobility	3.57 ± 0.96	−0.42	0.13	3.5	17.2
Activities of living	3.32 ± 0.91	−0.29	0.20	3.9	8.9
Working capacity	3.28 ± 0.96	−0.36	0.03	5.4	8.6
Social relationships	12.15 ± 2.91	−0.02	0.16	0.9	0.9
Social inclusion	2.60 ± 1.20	0.28	−0.81	22.4	7.2
Personal relationships	3.27 ± 0.90	−0.36	0.27	4.4	6.8
Sex life	2.96 ± 0.94	−0.23	0.04	8.5	4.2
Social support	3.31 ± 0.91	−0.35	0.28	4.4	8.3
Environment	12.05 ± 2.88	0.01	−0.05	0.5	0.5

12

Physical safety and security	2.85 ± 1.03	−0.01	−0.53	10.5	4.9
Home environment	2.97 ± 1.00	−0.09	−0.24	8.5	6.0
Financial resources	2.54 ± 1.19	0.33	−0.70	24.2	7.1
Opportunities for information and skills	2.95 ± 1.13	0.03	−0.72	11.0	9.2
Opportunities for recreation and leisure	2.89 ± 1.21	0.11	−0.89	14.2	11.0
Physical environment	3.25 ± 0.94	−0.37	0.08	5.3	7.4
Access to health and social care	3.38 ± 1.00	−0.48	0.06	6.0	11.5
Transport	3.26 ± 0.94	−0.31	0.08	4.9	8.2
Spirituality	13.07 ± 3.44	−0.32	−0.41	0.8	1.0
Spiritual	2.89 ± 1.14	−0.01	−0.78	13.4	7.9
Forgiveness	3.32 ± 1.23	−0.22	−0.84	7.5	20.2
Fear of the future	3.39 ± 1.22	−0.43	−0.83	8.4	19.2
Death and dying	3.46 ± 1.30	−0.51	−0.87	11.0	100.0

13

Reliability

The internal consistency was excellent, for the overall Cronbach's α coefficient of 0.93. The spirituality domain had an α of 0.66, which was slightly below the cut-off value of 0.70 for acceptable internal consistency. The other five domains were confirmed to have adequate internal consistency. The test-retest reliability showed a statistically significant ICC for all domains. The test-retest values were good, with the ICC ranging from 0.72 (spirituality domain) to 0.82 (independence domain) ($p < 0.001$). The results are reported in Table 3.

Table 3. Internal consistency and test-retest reliability of the WHOQOL-HIV BREF.

Domain	Cronbach's α coefficient (n = 1100)	ICC (95% CI) (n = 57)
Physical	0.71	0.76 (0.63–0.85)[***]
Psychological	0.70	0.73 (0.57–0.83)[***]
Independence	0.85	0.82 (0.71–0.89)[***]
Social relationships	0.71	0.80 (0.69–0.88)[***]
Environment	0.83	0.74 (0.59–0.84)[***]
Spirituality	0.66	0.72 (0.56–0.82)[***]

[***] $p < 0.001$

Construct validity

The CFA results showed that the six-domain structure of the WHOQOL-HIV BREF produced an acceptable fit to the data ($\chi^2 = 5662.69$, df = 362, p < 0.001; CFI = 0.81; RMSEA = 0.07 [90 % CI: 0.04–0.08]; AGFI = 0.87). Except for the item measuring spiritual, the factor loads of each item with their respective domain was acceptable, ranging from 0.35 to 0.89, which are shown in Figure 1.

Fig 1. The structure of the Chinese version of WHOQOL-HIV BREF from confirmatory factor analysis.

14

The six-factor structure of the WHOQOL-HIV BREF was tested across gender groups to evaluate factorial invariance. The results of configural invariance showed the invariance of the factor structure across gender groups: $\chi^2 = 6982.87$, $p < 0.001$, CFI = 0.808, and RMSEA = 0.072. The findings for metric invariance showed that the factor loadings were the same across gender groups：$\chi^2 = 6960.17$, $p < 0.001$, CFI = 0.809, and RMSEA = 0.073. And the change of CFI was 0.001, which was lower than 0.01. The Chinese version of WHOQOL-HIV BREF showed factorial invariance for PLWHA across gender groups.

Concurrent validity

The correlation coefficients of all domains with the two general measures (general QOL and general health status) and two component summary scores of SF-36 (PCS and MCS) are displayed in Table 4. All domains correlated with both general QOL and health status significantly ($p < 0.01$). The correlation coefficients were >0.40 ($r = 0.44–0.57$), with the exception of the association between the spirituality domain and the two items (QOL: $r = 0.33$; health status: $r = 0.36$). And the coefficients between all domains and two component summary scores were >0.40 ($r = 0.40–0.67$, $p < 0.01$). Generally, these results indicated satisfactory concurrent validity of the WHOQOL-HIV BREF.

Table 4. Concurrent validity of the WHOQOL-HIV BREF ($N = 1100$).

Domain	Correlation coefficient			
	General QOL	General health status	PCS	MCS
Physical	0.56[**]	0.54[**]	0.67[**]	0.66[**]
Psychological	0.54[**]	0.50[**]	0.55[**]	0.62[**]
Independence	0.57[**]	0.53[**]	0.63[**]	0.61[**]
Social relationships	0.47[**]	0.44[**]	0.46[**]	0.49[**]
Environment	0.53[**]	0.46[**]	0.49[**]	0.52[**]

15

| Spirituality | 0.33[**] | 0.36[**] | 0.40[**] | 0.49[**] |

[**] $p < 0.01$; PCS, physical component summary; MCS, mental component summary.

Convergent and discriminant validity

Concerning item-domain correlations, each item correlated with its respective domain score, and r coefficients ranged from 0.47 to 0.84 ($p < 0.01$). With regard to discriminant validity, the majority of items revealed a higher correlation with the respective domain than with other domains ($p < 0.01$). However, the item "spiritual" showed a higher correlation with the psychological domain ($r = 0.65$, $p < 0.01$) than with its respective (i.e., spirituality) domain ($r = 0.50$, $p < 0.01$). Generally, convergent and discriminant validity were considered as good (Table 5).

16

Table 5. Convergent and discriminant validity of the WHOQOL-HIV BREF ($N = 1100$).

Domain	Correlation coefficient range		Convergent validity		Discriminant validity	
	Convergent validity	Discriminant validity	Success/total	Percentage (%)	Success/total	Percentage (%)
Physical	0.66–0.72[**]	0.24–0.66[**]	4/4	100	4/4	100
Psychological	0.57–0.73[**]	0.15–0.67[**]	5/5	100	5/5	100
Independence	0.47–0.84[**]	0.02–0.68[**]	4/4	100	4/4	100
Social relationships	0.68–0.78[**]	0.26–0.57[**]	4/4	100	4/4	100
Environment	0.65–0.72[**]	0.19–0.64[**]	8/8	100	8/8	100
Spirituality	0.50–0.84[**]	0.14–0.65[**]	4/4	100	3/4	75

[**] $p < 0.01$

17

Known-group validity

A significant multivariate effect was found for CD4 count (Wilks' $\lambda = 0.956$, $F(12, 2184) = 4.12$, $p < 0.001$, $\eta_P^2 = 0.022$). Subsequent univariate F-tests, which are shown in Table 6, indicated that all six domains contributed to the multivariate effect. Among the three groups divided by CD4 count, the mean scores for the six domains in group C (CD4 count ≥ 500 cells/mm^3) were the highest, and the subjects having a CD4 count of <200 cells/mm^3 got the lowest scores ($p < 0.05$).

Table 6. Known-group validity for subgroups of participants by CD4 count ($N = 1100$).

Domain	Group A (<200 cells/mm^3)	Group B (200–499 cells/mm^3)	Group C (≥500 cells/mm^3)	F	η_P^2
Physical[abc]	12.63 ± 2.56	13.63 ± 2.97	14.30 ± 2.87	14.34^{***}	0.025
Psychological[abc]	11.01 ± 2.29	12.05 ± 2.75	12.68 ± 2.93	15.24^{***}	0.027
Social relationships[abc]	11.32 ± 2.32	11.99 ± 2.92	12.65 ± 2.96	10.43^{***}	0.019
Independence[abc]	12.09 ± 2.50	13.03 ± 2.86	13.77 ± 2.72	16.50^{***}	0.029
Environment[bc]	11.49 ± 2.33	11.93 ± 2.81	12.40 ± 3.10	5.09^{**}	0.009
Spirituality[c]	12.39 ± 2.86	12.98 ± 3.46	13.40 ± 3.51	3.81^{*}	0.007

$^{*}p < 0.05$; $^{**}p < 0.01$; $^{***}p < 0.001$

[a]Group A significantly different from Group B.

[b]Group B significantly different from Group C.

[c]Group A significantly different from Group C.

Regarding HIV stage, the multivariate effect was also significant (Wilks' $\lambda = 0.924$, $F(6, 1093) = 6.92$, $p < 0.001$, $\eta_P^2 = 0.076$), and follow-up tests indicated that the symptomatic participants had significantly lower scores than asymptomatic participants on physical (13.54 ± 3.03), psychological (11.69 ± 2.78), and independence (12.75 ± 2.73) domains ($p < 0.05$, see Table 7).

Table 7. Known-group validity for subgroups of participants by HIV stage ($N = 1100$).

Domain	Symptomatic	Asymptomatic	F	η_P^2
Physical	13.54 ± 3.03	14.10 ± 3.00	4.11^*	0.008
Psychological	11.69 ± 2.78	12.70 ± 2.81	15.43^{***}	0.029
Social relationships	12.02 ± 3.03	12.42 ± 2.77	2.39	0.005
Independence	12.75 ± 2.73	13.56 ± 2.78	10.28^{**}	0.020
Environment	12.01 ± 2.87	12.42 ± 2.85	2.49	0.005
Spirituality	13.62 ± 3.17	13.07 ± 3.58	3.07	0.006

$^*p < 0.05$; $^{**}p < 0.01$; $^{***}p < 0.001$

Discussion

Our results suggested that the WHOQOL-HIV BREF is reliable and valid in Chinese PLWHA. The skewness and kurtosis coefficients of all items and domains were in the acceptable range (-1.00 to 1.00), a result similar to previous studies conducted among Taiwanese HIV-infected patients and among aging Portuguese patients with HIV.[6,43] In line with other studies,[6,43] the ceiling effect of the item measuring pain and discomfort was above the accepted threshold of 20%. It is likely that the ceiling effect is dependent on population distribution.[43] Although previous studies have not reported the floor effects of WHOQOL-HIV BREF,[6,7,21,43] we detected floor effects for two items (social inclusion and financial resources).

Except for the spirituality domain, all domains showed satisfactory reliability. The results are in agreement with other reliability studies in Malaysia, Portugal, and Ethiopia.[21,43–45] Saddki and Pereira suggested that the content and size of the spirituality domain could result in lower reliability.[21,43] Tesfaye et al. noted that the limitation of the spirituality domain within this instrument should be recognized.[45] Chandra also indicated that the spirituality domain in the WHOQOL-HIV BREF may be inadequate, and he suggested that the WHOQOL-HIV having more items in the spirituality domain could be used to increase sensitivity in this regard.[46] We also

19

found that the WHOQOL-HIV BREF has satisfactory test-retest reliability, which is in agreement with the French version.[7]

The results of CFA suggested that the original six-domain structure could provide a generally good fit for our study data, which is consistent with other studies using WHOQOL-HIV BREF.[9,43,45] However, the exploratory factor analysis (EFA) of the WHOQOL-HIV BREF carried out with Portuguese and Malaysian HIV-positive patients yielded a five-factor model, which contradicts the original six-domain model.[21,44] Except for the EFA, Canavarro also conducted a CFA of WHOQOL-HIV BREF and found that both of the five-factor model and the original six-domain model fit relatively well.[44] Moreover, Peltzer's results from a multivariate logistic regression showed that four domains (psychological, independence, environment, and spirituality) were major predictors for overall QOL.[47] Some research studies have suggested that the original model fit would be improved if some items were modified.[44,45] The factor load of spiritual item on its respective domain (i.e. "Spirituality" domain) was 0.11, which was much lower than others. As previous suggested, in our study, we reassigned this item to the "Psychological" domain, and then assessed the construct validity again. The result showed that the factor load of spiritual item with "Psychological" domain was 0.67, and model fit was also improved, with the CFI = 0.87, RMSEA = 0.07 (90 % CI: 0.05–0.08), AGFI = 0.89.

The concurrent validity was demonstrated by the significant correlations with two general items and SF-36. All domains correlated significantly with self-perceived general QOL ($r = 0.33$–0.57, $p < 0.01$), health status ($r = 0.36$–0.54, $p < 0.01$), and

20

two component summary scores of SF-36 ($r = 0.40$–0.67, $p < 0.01$). The correlation

coefficient was comparable to that reported in the Malay version validation study[21]

but was somewhat lower than the result of other WHOQOL-HIV BREF validation

studies.[7,43] It was noted that the spirituality domain showed the lowest correlation

with the general QOL ($r = 0.33$, $p < 0.01$) and health status ($r = 0.36$, $p < 0.01$). This

is consistent with results of Saddki.[21] More specifically, from the findings of

discriminant validity, the item measuring spiritual showed a higher correlation with

the psychological domain ($r = 0.65$, $p < 0.01$) than with its initially assigned domain

(i.e., spirituality; $r = 0.50$, $p < 0.01$). Canavarro also found this in the European

Portuguese version, and he suggested that this item should be modified or reassigned

to the psychological domain.[44]

In support of the known-group validity, the WHOQOL-HIV BREF discriminated

between the CD4 count groups ($p < 0.05$), which is consistent with previous

studies.[44,48] We also observed that the subjects with higher CD4 counts revealed better

QOL. This was also reported by other researchers.[46,47] However, Pereira indicated that

domain scores were not significantly different across CD4 counts among aging adults

with HIV, and he implied that associations between biological markers and QOL may

conflict.[43] Another result was that the physical, psychological, and independence

domains discriminated relatively well between symptomatic and asymptomatic

PLWHA ($p < 0.05$). A multinational pilot study also showed that the domains of

physical and independence discriminated better than other domains between different

stages of HIV disease progression.[9] Other studies have found that the WHOQOL-HIV

21

BREF has a good validity in respect of disease stage, and asymptomatic PLWHA have better QOL than do symptomatic subjects.[15,21,45,48,49]

There limitations to this study that should be acknowledged. First, potential limitations are imposed by convenience sampling. All subjects were enrolled from health settings. The findings may thus not be generalizable to the entire population of PLWHA in China. Second, a longitudinal design might further measure the sensitivity of this instrument to changes in the HIV-related indicators such as CD4 count and HIV stage. Furthermore, there may be some problem in translation of the spirituality domain, and the next step of our research should be to assess the psychometric properties again after translating and modifying this domain.

Conclusions

The WHOQOL-HIV BREF revealed good psychometric characteristics among Chinese PLWHA. These findings offer promising support for the use of the WHOQOL-HIV BREF as a measure of QOL among Chinese PLWHA, and in cross-cultural comparative studies on QOL. Further studies on the spirituality domain should be carried out to ensure the effectiveness of WHOQOL-HIV BREF.

Acknowledgments

Competing Interests

The authors declare that they have no competing interests.

Funding

number 71473269 and 71673301. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Author contributions

BQ designed the research. YXZ and JL participated in the data collection and analysis. YXZ wrote the manuscript. All authors read and approved the final manuscript.

Ethics approval

Ethical protocol was obtained from the Bioethics Advisory Commission of China Medical University. All of the subjects provided written informed consent and voluntarily completed self-administered questionnaires.

Data sharing statement

No additional unpublished data.

References

1. National Health and Family Planning Commission of the People's Republic of China. 2015 China AIDS Response Progress Report. May 2015. Available: http://www.aidsdatahub.org/sites/default/files/publication/China_narrative_report_201 5.pdf. Accessed 16 January 2016.

2. NCAIDS, NCSTD, China CDC. Update on the AIDS/STD epidemic in China and main response in control and prevention in December, 2015. *Chin J AIDS STD* 2016;22(2):69. [In Chinese]

3. NCAIDS, NCSTD, China CDC. Update on the AIDS/STD epidemic in China and main response in control and prevention in February, 2016. *Chin J AIDS STD* 2016;22(4):223. [In Chinese]

4. Mutabazi-Mwesigire D, Seeley J, Martin F, Katamba A. Perceptions of quality of life among Ugandan patients living with HIV: a qualitative study. *BMC Public Health* 2014;14:343.

5. Mwesigire DM, Martin F, Seeley J, Katamba A. Relationship between CD4 count and quality of life over time among HIV patients in Uganda: a cohort study. *Health Qual Life Outcomes* 2015;13:144.

6. Hsiung PC, Fang CT, Wu CH, Sheng WH, Chen SC, Wang JD, et al. Validation of the WHOQOL-HIV BREF among HIV-infected patients in Taiwan. *AIDS Care* 2011; 23(8):1035-42.

7. Reychler G, Caty G, Vincent A, Billo S, Yombi JC. Validation of the French Version of the World Health Organization Quality of Life HIV Instrument. *PloS One*

2013;8(9):e73180.

8. Alonso J, Ferrer M, Gandek B, Ware JE Jr, Aaronson NK, Mosconi P, et al. Health-related quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Assessment (IQOLA) Project. *Qual Life Res* 2004;13(2):283-298.

9. O'Connell KA, Skevington SM. An International Quality of Life Instrument to Assess Well-being in Adults Who are HIV-Positive: A Short Form of the WHOQOL-HIV (31 items). *AIDS Behavior* 2012;16(2):452-460.

10. Starace F, Cafaro L, Abrescia N, Chirianni A, Izzo C, Rucci P, et al. Quality of life assessment in HIV-positive persons: application and validation of the WHOQOL-HIV, Italian version. *AIDS Care* 2002;14(3):405-15.

11. Wu AW. Quality of life assessment comes of age in the era of highly active antiretroviral therapy. *AIDS* 2000;14(10):1449-51.

12. Weinfurt KP, Willke RJ, Glick HA, Freimuth WW, Schulman KA. Relationship between CD4 Count, Viral Burden, and Quality of Life over Time in HIV-1-Infected Patients. *Med Care* 2000;38(4):404-10.

13. Skevington S M, Norweg S, Standage M; WHOQOL HIV group. Predicting quality of life for people living with HIV: international evidence from seven cultures. *AIDS Care* 2015;22(5):614-622.

14. Mutabazi-Mwesigire D, Katamba A, Martin F, Seeley J, Wu AW. Factors That Affect Quality of Life among People Living with HIV Attending an Urban Clinic in Uganda: A Cohort Study. *Plos One* 2015;10(6):e0126810.

15. Nglazi MD, West SJ, Dave JA, Levitt NS, Lambert EV. Quality of life in individuals living with HIV/AIDS attending a public sector antiretroviral service in Cape Town, South Africa. *BMC Public Health* 2014;14:676.

16. Nobre N, Pereira M, Sutinen J, Canavarro MC, Sintonen H, Roine RP. Quality of life of people living with HIV/AIDS: a cross-country comparison study of Finland and Portugal. *AIDS Care* 2016;28(7):873-7.

17. Balderson BH, Grothaus L, Harrison RG, McCoy K, Mahoney C, Catz S. Chronic illness burden and quality of life in an aging HIV population. *AIDS Care* 2013;25(4): 451-458.

18. Lubeck DP, Fries JF. Assessment of quality of life in early stage HIV-infected persons: data from the AIDS Time-Oriented Health Outcome Study (ATHOS). *Qual Life Res* 1997;6(6):494-506.

19. Peterman AH, Cella D, Mo F, McCain N. Psychometric validation of the revised Functional Assessment of Human Immunodeficiency Virus Infection (FAHI) quality of life instrument. *Qual Life Res* 1997;6(6):572-584.

20. WHOQOL-HIV Group. Initial steps to developing the World Health Organization's Quality of Life Instrument (WHOQOL) module for international assessment in HIV/AIDS. *AIDS Care* 2003;15(3):347-357.

21. Saddki N, Noor MM, Norbanee TH, Rusli MA, Norzila Z, Zaharah S, et al. Validity and reliability of the Malay version of WHOQOL-HIV BREF in patients with HIV infection. *AIDS Care* 2009;21(10):1271-8.

22. Bowden A, Fox-Rushby JA. A systematic and critical review of the process of

translation and adaptation of generic health-related quality of life measures in Africa, Asia, Eastern Europe, the Middle East, South America. *Soc Sci Med* 2003;57(7):1289-306.

23. O'Connell K, Skevington S, Saxena S; WHOQOL HIV Group. Preliminary development of the World Health Organsiation's quality of life instrument (WHOQOL-HIV): analysis of the pilot version. *Soc Sci Med* 2003;57(7):1259-75.

24. WHOQOL-HIV Group. WHOQOL-HIV for quality of life assessment among people living with HIV and AIDS: results from the field test. *AIDS Care* 2004;16(7):882-9.

25. Cai NQ, Kang J, Xu DL, Hao YT, He LY. Qualitative interview on modification of WHOQOL-HIV. *J Tra Chin Med* 2012;53(10):839-842. [In Chinese]

26. Liu WM, He LY, Wang J, Liu BY, Mark van OMMEREN, Fang JQ, et al. The introduce and usage of WHOQOL-HIV BREF instrument in Chinese. *Chin J Info Tradit Chin* 2009;16(10):1-2. [In Chinese]

27. Fu ST, Tuan YC, Yen MY, Wu WH, Huang CW, Chen WT, et al. Psychometric properties of the World Health Organization quality of life assessment-brief in methadone patients: a validation study in northern Taiwan. *Harm Reduct J* 2013;10:37.

28. Ming Z, Prybylski D, Cheng F, Airawanwat R, Zhu Q, Liu W, et al. Two-Year Prospective Cohort Study on Quality of Life Outcomes Among People Living With HIV After Initiation of Antiretroviral Therapy in Guangxi, China. *J Assoc Nurses AIDS Care* 2014;25(6):603-613.

29. Huang D, Sangthong R, Mcneil E, Chongsuvivatwong V, Zheng W, Yang X. Effects of a Phone Call Intervention to Promote Adherence to Antiretroviral Therapy and Quality of Life of HIV/AIDS Patients in Baoshan, China: A Randomized Controlled Trial. *AIDS Res Treat* 2013;2013:580974.

30. MM Shoukri, MH Asyali, A Donner. Sample size requirements for the design of reliability study: Review and new results. *Statistical Methods in Medical Research* 2004;13(4):251-271.

31. CDC. 1993 revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. *MMWR Recomm Rep* 1992;41(RR-17):1-19.

32. CDC. Comparison of the revised World Health Organization and CDC surveillance case definitions and staging systems for HIV Infection. *MMWR Recomm Rep* 2008;57(RR10):10-11.

33. Ware J, Sherbourne SD. The MOS 36-item short form health survey (SF-36). 1. Conceptual frame-work and item selection. *Medical Care* 1992;30(6):473-481.

34. Meng YJ, Li NX, Liu CJ, Chen JH, Song YC, Qian ZS. Quality of life and hostile mentality trend of patients with HIV/AIDS in China. *Public Health* 2008;122(4):404-11.

35. Bing EG, Hays RD, Jacobson LP, Chen B, Gange SJ, Kass NE, et al. Health-related quality of life among people with HIV disease: Results from the Multicenter AIDS Cohort Study. *Qual Life Res* 2000;9(1):55-63.

36. Zhu Y X, Li T, Fan S R, Liu XP, Liang YH, Liu P. Health-related quality of life as

measured with the Short-Form 36 (SF-36) questionnaire in patients with recurrent vulvovaginal candidiasis. *Health Qual Life Outcomes* 2016;14(1):1-6.

37. Hays RD, Sherbourne CD, Mazel RM. The RAND 36-Item Health Survey 1.0. *Health Economics* 1993;2(3):217-27.

38. Holmes W, Shea J. Performance of a new, HIV/AIDS-targeted quality of life (HAT-QoL) instrument in asymptomatic seropositive individuals. *Qual Life Res* 1997;6(6):561-571.

39. van Lummel RC, algaard S, Hobert MA, Maetzler W, van Dieën JH, Galindo-Garre F, et al. Intra-Rater, Inter-Rater and Test-Retest Reliability of an Instrumented Timed Up and Go (iTUG) Test in Patients with Parkinson's Disease. *Plos One* 2016;11(3):e0151881.

40. Byrne BM. Structural equation modeling with Lisrel, Prelis, and Simplis. Basic concepts, applications, and programming. *Structural Equation Modeling A Multidisciplinary Journal* 1998;7(4):640-643.

41. Yekaninejad MS, Pakpour A H, Tadakamadla J, Kumar S, Mosavi SH, Fridlund B, et al. Oral-health-related quality of life in patients with cancer: cultural adaptation and the psychometric testing of the Persian version of EORTC QLQ-OH17. *Support Care Cancer* 2015;23(5):1215-24.

42. Jiang XH, Shen ZZ, Zhang NN, Liao HX, Xu HY. Research on reliability and validity of questionnaire. *Mod Prev Med* 2010;37(3):429-431. [In Chinese]

43. Pereira M, Martins A, Alves S, Canavarro MC. Assessing quality of life in

middle-aged and older adults with HIV: psychometric testing of the WHOQOL-HIV-Bref. *Qual Life Res* 2014;23(9):2473-9.

44. Canavarro MC, Pereira M. Factor structure and psychometric properties of the European Portuguese version of a questionnaire to assess quality of life in HIV-infected adults: the WHOQOL-HIV-Bref. *AIDS Care* 2012;24(6):799-807.

45. Tesfaye M, Olsen MF, Medhin G, Friis H, Hanlon C, Holm L. Adaptation and validation of the short version WHOQOL-HIV in Ethiopia. *Int J Ment Health Syst* 2016;10:29.

46. Chandra PS, Gandhi C, Satishchandra P, Kamat A, Desai A, Ravi V, et al. Quality of life in HIV subtype C infection among asymptomatic subjects and its association with CD4 counts and viral loads-a study from South India. *Qual Life Res* 2006;15(10):1597-1605.

47. Peltzer K, Phaswanamafuya N. Health-related quality of life in a sample of HIV-infected South Africans. *Afr J AIDS Res* 2008;7(2):209-218.

48. Tran BX. Quality of life outcomes of antiretroviral treatment for HIV/AIDS patients in Vietnam. *Plos One* 2012;7(7):e41062.

49. Zimpel RR, Fleck MP. Quality of life in HIV-positive Brazilians: application and validation of the WHOQOL-HIV, Brazilian version. *AIDS Care* 2007;19(7):923-30.
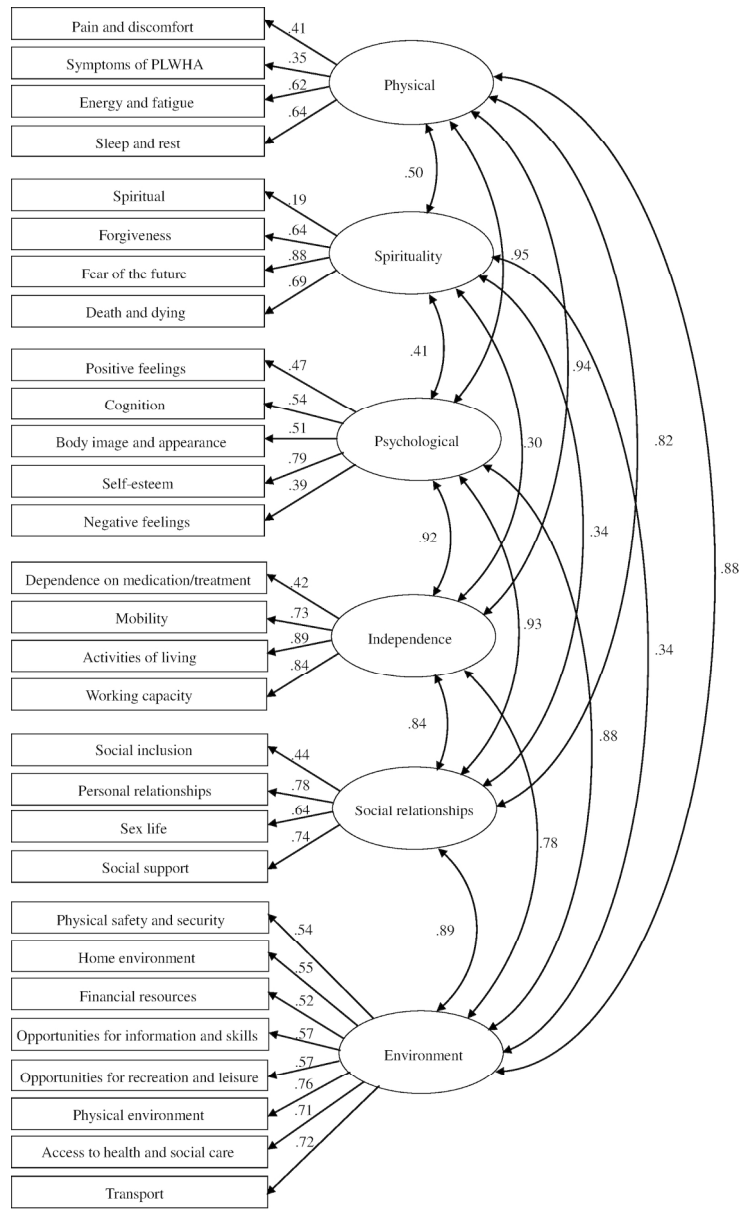
Fig 1. The structure of the Chinese version of the WHOQOL-HIV BREF based on confirmatory factor analysis.

134x222mm (300 x 300 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2, 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4, 5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6, 7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6, 7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7, 8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7, 8
Bias	9	Describe any efforts to address potential sources of bias	*6*

Study size	10	Explain how the study size was arrived at	6, 7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8, 9
		(*b*) Describe any methods used to examine subgroups and interactions	8, 9
		(*c*) Explain how missing data were addressed	8
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	6, 7
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6, 9
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9, 10
		(b) Indicate number of participants with missing data for each variable of interest	6
Outcome data	15*	Report numbers of outcome events or summary measures	9-19
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	14-19
		(*b*) Report category boundaries when continuous variables were categorized	9-19

		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	19, 20, 21, 22
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	22
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19, 20, 21, 22
Generalisability	21	Discuss the generalisability (external validity) of the study results	22
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	22

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Psychometric properties of the Chinese version of the WHOQOL-HIV BREF to assess quality of life among people living with HIV/AIDS: A cross-sectional study

SCHOLARONE™
Manuscripts

Psychometric properties of the Chinese version of the WHOQOL-HIV BREF to assess quality of life among people living with HIV/AIDS: A cross-sectional study

Yaxin Zhu[1], Jie Liu[2], Bo Qu[2]*

[1]Department of Social Medicine, School of Public Health, China Medical University, Shenyang, Liaoning Province, P.R. China

[2]Department of Health Statistics, School of Public Health, China Medical University, Shenyang, Liaoning Province, P.R. China

* Correspondence to: Bo Qu, M.D., Ph.D., Department of Health Statistics, School of Public Health, China Medical University, 77 Puhe road, Shenyang North New Area, Shenyang 110122, People's Republic of China.

Tel: 86-24-31939588

Fax: 86-24-31939588

E-mail: qubo6666@163.com

1

Abstract

Objectives: This study aims to assess the psychometric properties of the Chinese version of the WHOQOL-HIV BREF.

Design: Cross-sectional study.

Setting: Center for Disease Control and Prevention (CDC) and infectious disease hospitals in three Chinese provinces.

Participants: Sample of 1100 people living with HIV/AIDS (PLWHA)

Interventions: We recruited 1100 PLWHA to evaluate their QOL using the WHOQOL-HIV BREF. Of these participants, 57 were randomly selected to repeat the QOL evaluation 2 weeks later.

Main outcome measures: The reliability of the WHOQOL-HIV BREF was assessed in terms of its internal consistency and test-retest reliability. The construct, concurrent, convergent, discriminant, and known-group validity were also analysed. In addition, the factorial invariance across genders was assessed.

Results: Cronbach's α coefficient for the overall scale was 0.93. Except for the spirituality domain, which had an α below 0.70 (0.66), the other five domains showed adequate internal consistency. The test-retest reliability revealed a statistically significant intraclass correlation coefficient (ICC) of 0.72-0.82 ($p < 0.001$). Confirmatory factor analysis found that the six-domain structure produced an acceptable fit to the data. The instrument showed factorial invariance across gender groups. All domains were significantly correlated with the general items and the SF-36 ($p < 0.01$). The correlation coefficients were > 0.40 ($r = 0.40$-0.67), except for

the association between the spirituality domain and two general items (QOL: $r = 0.33$; health status: $r = 0.36$). Subjects with lower CD4 counts had lower scores for all domains ($p < 0.05$). Symptomatic participants had significantly lower scores than asymptomatic participants on the physical, psychological, and independence domains ($p < 0.05$).

Conclusions: The WHOQOL-HIV BREF revealed good psychometric characteristics among Chinese PLWHA. These findings offer promising support for the use of the WHOQOL-HIV BREF as a measure of QOL among Chinese PLWHA and in cross-cultural comparative studies on QOL.

Strengths and limitations of this study

1. This study offers promising support for the use of the WHOQOL-HIV BREF as a measure of quality of life (QOL) among Chinese people living with HIV/AIDS (PLWHA) and in cross-cultural comparative studies on QOL.

2. In our study, the tool's psychometric properties were analysed comprehensively.

3. The study sample was recruited from three provinces encompassing the geographic diversity of northern, central, and southern China.

4. A longitudinal design might further measure the sensitivity of this instrument to changes in HIV-related indicators such as CD4 count and HIV stage.

Introduction

The number of people living with HIV/AIDS (PLWHA) in China increased from 351,709 in 2011[1] to 577,423 in 2015.[2] According to national data, as of February 2016, China had 591,632 PLWHA.[3] Although the number of PLWHA is rising, the fatality rate for AIDS has decreased gradually since 2011 as the result of increasing availability of highly active antiretroviral therapy (HAART).[1] The national epidemic data showed that the number of PLWHA receiving HAART increased from 295,358 in 2014[1] to 382,139 in 2015.[2] The expanded use of HAART has increased the life expectancy of PLWHA.[4,5]

Since the advent of HAART, AIDS has progressed from an acute fatal infection into a manageable chronic disease.[4,6] The evaluation of quality of life (QOL) has proven to be crucial in chronic disease treatment over the past decades.[7,8] Moreover, because AIDS is an incurable disease, PLWHA will continue to suffer from the disease.[7] Thus, QOL assessments have recently become an essential element in AIDS care,[7,9-12] and improving the QOL of PLWHA has become a priority.[13]

In recent years, there has been much research on AIDS-related QOL.[12-17] To better understand and evaluate the QOL of PLWHA, a reliable and valid measurement tool for QOL is important.[7,11] Several instruments have been applied to assess the QOL of PLWHA such as the EQ-5D,[15] SF-36,[17] WHOQOL-HIV BREF,[16] MOS-HIV,[14] AIDS-HAQ,[18] and FAHI.[19] Compared to generic questionnaires, AIDS-specific questionnaires have greater relevance and sensitivity.[20] Reychler also suggested that disease-specific tools for assessing QOL are of particular relevance for HIV-infected

4

patients.[7] Some instruments have been developed within a single culture, particularly the Western culture. In addition, versions that have been translated into a different language often present less equality between the semantics and the concept, as demonstrated by their poorer psychometric characteristics.[13,21,22] Furthermore, previous studies have suggested that a cross-culturally valid QOL measure may be important for assessing health delivery in various cultural conditions.[6,20]

In 2003, the WHO developed the WHOQOL-HIV with 120 items (100 generic items and 20 HIV-related items).[20,23] The WHOQOL-HIV is a multi-dimensional instrument developed through a multi-national collaboration. Furthermore, the instrument has been proven by a field test to be promising for assessing QOL in different cultural contexts.[24] The Chinese version of the WHOQOL-HIV was developed by the research team from Sun Yat-sen University and China Academy of Chinese Medical Sciences.[25,26] The translation and cross-cultural adaptation of the original English version of the WHOQOL-HIV into Chinese were performed according to the method proposed by the WHO. The implementation of this method includes the following steps: forward translation, expert panel review, back-translation, pre-test and cognitive interviews, and formulation of the final version.[25,26]

The WHOQOL-HIV BREF is the short version of the WHOQOL-HIV and includes 31 items covering six domains.[9] Additionally, it has been translated into different languages and has been proven to be reliable and valid.[9,16,27] Although a few studies have applied this instrument to Chinese PLWHA,[28,29] its psychometric properties have

5

not been fully assessed. This study was designed to assess the psychometric properties

of the WHOQOL-HIV BREF among Chinese PLWHA. These findings may be of

great importance for better understanding their QOL.

Materials and Methods

Ethics statement

The ethical protocol was obtained from the Bioethics Advisory Commission of

China Medical University. The investigators informed all participants about the

purpose of the study and assured them before the research began that their privacy

would be protected. All subjects provided written informed consent and voluntarily

completed self-administered questionnaires.

Study population and procedures

A convenience sample was recruited from five cities (Shenyang, Dalian, Dandong,

Zhengzhou, Ningbo) encompassing the geographic diversity of northern, central, and

southern China. Shenyang, Dalian, and Dandong are three cities in the Liaoning

province, which is situated in the northeast region of China. Zhengzhou is the capital

of the Henan province in the central region of China. Ningbo is a city in the Zhejiang

province, which is in the southern region of China. The inclusion criteria were that

participants were 18 years or older, infected with HIV, and without cognitive

impairment. In total, 1201 PLWHA were recruited from local Center for Disease

Control and Prevention (CDC) branches and infectious disease hospitals between

February 2015 and January 2016. All subjects received a self-administered

questionnaire and were compensated with 50 Chinese Yuan after completing the

questionnaire. To ensure the quality of the questionnaire, specially trained investigators inspected the questionnaires after their completion and identified those that were missing answers or had more than one answer. If > 20% of the responses on one questionnaire were missing, the questionnaire was considered invalid. Questionnaires with valid responses were collected from 1100 participants total, and the valid response rate was 91.6%. Shoukri et al. suggested that the required sample size for a test-retest reliability study to estimate an ICC of 0.8 and a 95% CI with a width of 0.2 (i.e., the value of ICC is between 0.7 and 0.9) was 52.[30] To examine the test-retest reliability, 57 participants were randomly selected to complete the QOL evaluation again 2 weeks later.

Questionnaire

The questionnaire comprised four sections including socio-demographic information, HIV-related characteristics, the WHOQOL-HIV BREF, and the SF-36. The socio-demographic information included age, gender, and work status. The HIV-related characteristics consisted of HIV stage, CD4 cell counts, mode of HIV transmission, and time since diagnosis. As categorized by the clinically meaningful cut-off points,[31] CD4 cell counts were stratified into three groups. The HIV stage was divided into two groups: HIV-asymptomatic and HIV-symptomatic.[13,21,32]

The WHOQOL-HIV BREF consisted of 31 items rated on a five-point Likert scale. Among the 31 items, 29 domain-specific items were used to measure individual QOL across six domains. The other two items were used to measure participants' perception of their general QOL and health status. The domain scores were calculated by

7

multiplying the mean of all items within the domain by 4. All domain scores ranged

from 4 to 20. Higher scores in each domain indicated higher QOL for that domain.

The SF-36 is a generic QOL measurement tool that has proven to be reliable and

clinically valid for assessing the QOL of PLWHA.[33-36] The SF-36 included 36 items

covering 8 domains, and the domain scores formed two summary scores:[7] the physical

component summary (PCS) and the mental component summary (MCS) scores,

which ranged from 0 to 100.[37,38] Higher scores indicated a better QOL. The reliability

of this instrument in our study was satisfactory, with the alpha equal to 0.93.

Statistical analysis

Missing data were replaced by a median. The mean, standard deviation (SD),

skewness, kurtosis, floor effects, and ceiling effects of each item and domain were

computed. Floor or ceiling effects were significant if the percentage of subjects with

the lowest or the highest score was > 20%.[27,39] A Cronbach's α coefficient of ≥ 0.70

was considered to be an acceptable level of internal consistency. An intraclass

correlation coefficient (ICC) was applied for test-retest reliability, with an ICC ≥ 0.70

indicating good test-retest reliability.[40]

To test the construct validity, a confirmatory factor analysis (CFA) was used.[41]

Goodness-of-fit was evaluated using the indexes including χ^2, root mean square error

of approximation (RMSEA), comparative fit index (CFI), and adjusted

goodness-of-fit index (AGFI). An RMSEA value < 0.08 and a CFI value > 0.90

indicated a good fit.[41] For AGFI, a value > 0.85 was considered to be an adequate

model fit.[41] A multiple-group CFA analysis was conducted to investigate whether the

WHOQOL-HIV BREF measured the same constructs across gender groups. First, we assessed the configural invariance. The next step involved assessing the metric invariance by examining if the factor loadings were the same across gender groups. Changes in CFI (ΔCFI $\leq$ 0.01) were used to demonstrate factorial invariance across groups.[13,42]

Regarding concurrent validity, all domains were correlated with two general items (QOL and health status) and the SF-36.[7,25] The scale's convergent and discriminant validity were tested by calculating item-domain Pearson's correlations. A correlation coefficient > 0.4 for items and their respective domains was considered to be satisfactory.[7,27] Items revealing correlations with their respective domains that were higher than those with other domains indicated good discriminant validity.[43]

Known-group validity was used to test how well the WHOQOL-HIV BREF discriminated among the subgroups of participants with regard to CD4 count and HIV stage. A multivariate analysis of variance (MANOVA) was conducted to analyse the known-group validity. Post hoc tests were conducted to examine significant differences in domain scores among the three CD4 groups. It was hypothesized that HIV-symptomatic participants and PLWHA with lower CD4 counts would have significantly lower QOL domain scores. Values of $p < 0.05$ were considered to be statistically significant. SPSS 19.0 and LISREL 8.5 software for Windows were used.

Results

Basic characteristics of the study sample

The mean age of the 1100 participants was 39.62 years, with an SD of 12.73. Most

9

of the participants were male (965, 87.7%). Of the 1100 participants, 713 (64.8%)

were infected with HIV through male homosexual sex. 691 (62.8%) were

asymptomatic. The average time since diagnosis was 3.91 years (SD = 2.85). The

socio-demographic and HIV-related characteristics are shown in Table 1.

Table 1. Socio-demographic and HIV-related characteristics of the sample ($N = 1100$).

Characteristic	Number	Percentage
Gender		
Male	965	87.7%
Female	135	12.3%
Work status		
Employed full-time	643	58.4%
Employed part-time	420	38.2%
Unemployed	37	3.4%
Marital status		
Single	450	40.9%
Married	443	40.3%
Divorced/Widowed	207	18.8%
Education level		
Primary school or lower	138	12.5%
Junior high school	331	30.1%
Senior high school	235	21.4%
Junior college	184	16.7%
College or above	212	19.3%
Residence		
Shenyang	193	17.6%
Dalian	205	18.6%
Dandong	123	11.2%
Zhengzhou	381	34.6%
Ningbo	198	18.0%
Monthly income (Yuan)		
<1000	222	20.2%
1001–2000	256	23.3%
2001–3000	314	28.5%
≥3001	308	28.0%
HIV stage		
Symptomatic	409	37.2%
Asymptomatic	691	62.8%
CD4 count (cells/mm^3)		
<200	99	9.0%
200–499	642	58.4%

10

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

≥500	359	32.6%
Mode of HIV transmission		
Male homosexual sex	713	64.8%
Heterosexual sex	210	19.1%
Drug abuse	11	1.0%
Blood product	112	10.2%
Unknown	54	4.9%

Score distributions

The descriptive statistics of each item and domain are displayed in Table 2. The skewness and kurtosis coefficients of all items and domains ranged from -1.00 to 1.00, which were acceptable. No significant floor or ceiling effects were found in the six domains. However, the item measuring pain and discomfort showed a significant ceiling effect (35.9%), and floor effects were detected in the items measuring social inclusion (22.4%) and financial resources (24.2%). Across domains, the physical domain had the highest score (13.76 ± 2.94), and the environment domain score was the lowest (12.05 ± 2.88).

11

Table 2. Descriptive statistics of the WHOQOL-HIV BREF (N = 1100).

Domain or item	Mean ± SD	Skewness	Kurtosis	Floor (%)	Ceiling (%)
General QOL	3.27 ± 0.92	−0.18	0.5	5.0	9.8
General health status	3.10 ± 0.94	−0.09	−0.09	5.2	6.6
Physical	13.76 ± 2.94	−0.19	−0.25	0.1	1.5
Pain and discomfort	4.01 ± 0.99	−0.98	0.46	1.8	35.9
Symptoms of PLWHA	3.48 ± 1.08	−0.49	−0.64	3.9	15.3
Energy and fatigue	3.19 ± 1.19	−0.02	−0.91	7.9	17.6
Sleep and rest	3.08 ± 1.04	−0.19	−0.33	8.7	8.3
Psychological	12.16 ± 2.81	0.26	−0.16	0.1	0.8
Positive feelings	2.83 ± 1.09	0.04	−0.71	12.5	5.9
Cognition	2.90 ± 1.00	0.01	−0.47	8.3	5.0
Body image and appearance	3.07 ± 1.11	0.10	−0.50	8.1	13.3
Self-esteem	3.17 ± 0.98	−0.25	−0.18	5.8	7.4
Negative feelings	3.24 ± 0.99	0.03	−0.25	4.0	12.5
Independence	13.19 ±2.82	−0.13	0.17	0.2	1.6
Dependence on medication/treatment	3.02 ± 1.12	0.07	−0.78	8.3	10.7
Mobility	3.57 ± 0.96	−0.42	0.13	3.5	17.2
Activities of living	3.32 ± 0.91	−0.29	0.20	3.9	8.9
Working capacity	3.28 ± 0.96	−0.36	0.03	5.4	8.6
Social relationships	12.15 ± 2.91	−0.02	0.16	0.9	0.9
Social inclusion	2.60 ± 1.20	0.28	−0.81	22.4	7.2
Personal relationships	3.27 ± 0.90	−0.36	0.27	4.4	6.8
Sex life	2.96 ± 0.94	−0.23	0.04	8.5	4.2
Social support	3.31 ± 0.91	−0.35	0.28	4.4	8.3
Environment	12.05 ± 2.88	0.01	−0.05	0.5	0.5

12

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

Physical safety and security	2.85 ± 1.03	−0.01	−0.53	10.5	4.9
Home environment	2.97 ± 1.00	−0.09	−0.24	8.5	6.0
Financial resources	2.54 ± 1.19	0.33	−0.70	24.2	7.1
Opportunities for information and skills	2.95 ± 1.13	0.03	−0.72	11.0	9.2
Opportunities for recreation and leisure	2.89 ± 1.21	0.11	−0.89	14.2	11.0
Physical environment	3.25 ± 0.94	−0.37	0.08	5.3	7.4
Access to health and social care	3.38 ± 1.00	−0.48	0.06	6.0	11.5
Transport	3.26 ± 0.94	−0.31	0.08	4.9	8.2
Spirituality	13.07 ± 3.44	−0.32	−0.41	0.8	1.0
Spiritual	2.89 ± 1.14	−0.01	−0.78	13.4	7.9
Forgiveness	3.32 ± 1.23	−0.22	−0.84	7.5	20.2
Fear of the future	3.39 ± 1.22	−0.43	−0.83	8.4	19.2
Death and dying	3.46 ± 1.30	−0.51	−0.87	11.0	25.1

13

Reliability

The internal consistency was excellent, with an overall Cronbach's α coefficient of 0.93. The spirituality domain had an α of 0.66, which was slightly below the cut-off value of 0.70 for acceptable internal consistency. The other five domains were confirmed to have adequate internal consistency. The test-retest reliability showed a statistically significant ICC for all domains. The test-retest values were good, with the ICC ranging from 0.72 (spirituality domain) to 0.82 (independence domain) ($p <$ 0.001). The results are reported in Table 3.

Table 3. Internal consistency and test-retest reliability of the WHOQOL-HIV BREF.

Domain	Cronbach's α coefficient (n = 1100)	ICC (95% CI) (n = 57)
Physical	0.71	0.76 (0.63–0.85)[***]
Psychological	0.70	0.73 (0.57–0.83)[***]
Independence	0.85	0.82 (0.71–0.89)[***]
Social relationships	0.71	0.80 (0.69–0.88)[***]
Environment	0.83	0.74 (0.59–0.84)[***]
Spirituality	0.66	0.72 (0.56–0.82)[***]

[***] $p < 0.001$

Construct validity

The CFA results showed that the six-domain structure of the WHOQOL-HIV BREF produced an acceptable fit to the data (χ^2 = 5662.69, df = 362, p < 0.001; CFI = 0.81; RMSEA = 0.07 [90% CI: 0.04-0.08]; AGFI = 0.87). Except for the item measuring spiritual, the factor load of each item with its respective domain was acceptable, ranging from 0.35 to 0.89, as shown in Figure 1.

Fig 1. The structure of the Chinese version of the WHOQOL-HIV BREF based on confirmatory factor analysis.

14

The six-factor structure of the WHOQOL-HIV BREF was tested across gender groups to evaluate factorial invariance. The results of configural invariance showed the invariance of the factor structure across gender groups: $\chi^2 = 6982.87$, p < 0.001, CFI = 0.808, and RMSEA = 0.072. The findings for metric invariance showed that the factor loadings were the same across gender groups： $\chi^2 = 6960.17$, p < 0.001, CFI = 0.809, and RMSEA = 0.073. In addition, the change of CFI was 0.001, which was lower than 0.01. The Chinese version of the WHOQOL-HIV BREF showed factorial invariance for PLWHA across gender groups.

Concurrent validity

The correlation coefficients of all domains with the two general measures (general QOL and general health status) and two component summary scores of the SF-36 (PCS and MCS) are displayed in Table 4. All domains correlated with both general QOL and health status significantly ($p < 0.01$). The correlation coefficients were > 0.40 ($r = 0.44$-0.57), with the exception of the association between the spirituality domain and the two items (QOL: $r = 0.33$; health status: $r = 0.36$). In addition, the coefficients between all domains and two component summary scores were > 0.40 ($r = 0.40$–0.67, $p < 0.01$). Generally, these results indicated satisfactory concurrent validity of the WHOQOL-HIV BREF.

Table 4. Concurrent validity of the WHOQOL-HIV BREF (N = 1100).

Domain	Correlation coefficient			
	General QOL	General health status	PCS	MCS
Physical	0.56[**]	0.54[**]	0.67[**]	0.66[**]
Psychological	0.54[**]	0.50[**]	0.55[**]	0.62[**]
Independence	0.57[**]	0.53[**]	0.63[**]	0.61[**]
Social relationships	0.47[**]	0.44[**]	0.46[**]	0.49[**]
Environment	0.53[**]	0.46[**]	0.49[**]	0.52[**]

15

| Spirituality | 0.33[**] | 0.36[**] | 0.40[**] | 0.49[**] |

[**] $p < 0.01$; PCS, physical component summary; MCS, mental component summary.

Convergent and discriminant validity

Concerning item-domain correlations, each item correlated with its respective domain score, and r coefficients ranged from 0.47 to 0.84 ($p < 0.01$). With regard to discriminant validity, the majority of items revealed a higher correlation with their respective domains than with other domains ($p < 0.01$). However, the item **"spiritual"** showed a higher correlation with the psychological domain ($r = 0.65$, $p < 0.01$) than with its respective (i.e., spirituality) domain ($r = 0.50$, $p < 0.01$). Generally, convergent and discriminant validity were considered to be good (Table 5).

Table 5. Convergent and discriminant validity of the WHOQOL-HIV BREF ($N = 1100$).

Domain	Correlation coefficient range		Convergent validity		Discriminant validity	
	Convergent validity	Discriminant validity	Success/total	Percentage (%)	Success/total	Percentage (%)
Physical	0.66–0.72[**]	0.24–0.66[**]	4/4	100	4/4	100
Psychological	0.57–0.73[**]	0.15–0.67[**]	5/5	100	5/5	100
Independence	0.47–0.84[**]	0.02–0.68[**]	4/4	100	4/4	100
Social relationships	0.68–0.78[**]	0.26–0.57[**]	4/4	100	4/4	100
Environment	0.65–0.72[**]	0.19–0.64[**]	8/8	100	8/8	100
Spirituality	0.50–0.84[**]	0.14–0.65[**]	4/4	100	3/4	75

[**]$p < 0.01$

17

Known-group validity

A significant multivariate effect was found for CD4 counts (Wilks' λ = 0.956, F(12, 2184) = 4.12, p < 0.001, η_P^2 = 0.022). Subsequent univariate F-tests, which are shown in Table 6, indicated that all six domains contributed to the multivariate effect. Among the three groups divided by CD4 count, the mean scores for the six domains in group C (CD4 count $\geq$ 500 cells/mm^3) were the highest, and the subjects with a CD4 count < 200 cells/mm^3 showed the lowest scores (p < 0.05).

Table 6. Known-group validity for subgroups of participants by CD4 count (N = 1100).

Domain	Group A (<200 cells/mm^3)	Group B (200–499 cells/mm^3)	Group C ($\geq$500 cells/mm^3)	F	η_P^2
Physical[abc]	12.63 ± 2.56	13.63 ± 2.97	14.30 ± 2.87	14.34[***]	0.025
Psychological[abc]	11.01 ± 2.29	12.05 ± 2.75	12.68 ± 2.93	15.24[***]	0.027
Social relationships[abc]	11.32 ± 2.32	11.99 ± 2.92	12.65 ± 2.96	10.43[***]	0.019
Independence[abc]	12.09 ± 2.50	13.03 ± 2.86	13.77 ± 2.72	16.50[***]	0.029
Environment[bc]	11.49 ± 2.33	11.93 ± 2.81	12.40 ± 3.10	5.09[**]	0.009
Spirituality[c]	12.39 ± 2.86	12.98 ± 3.46	13.40 ± 3.51	3.81[*]	0.007

[*] p < 0.05; [**] p < 0.01; [***] p < 0.001

[a]Group A significantly different from Group B.

[b]Group B significantly different from Group C.

[c]Group A significantly different from Group C.

Regarding HIV stage, the multivariate effect was also significant (Wilks' λ = 0.924, F(6, 1093) = 6.92, p < 0.001, η_P^2 = 0.076), and follow-up tests indicated that the symptomatic participants had significantly lower scores than asymptomatic participants in the physical (13.54 ± 3.03), psychological (11.69 ± 2.78), and independence (12.75 ± 2.73) domains (p < 0.05, see Table 7).

Table 7. Known-group validity for subgroups of participants by HIV stage (N = 1100).

Domain	Symptomatic	Asymptomatic	F	η_P^2
Physical	13.54 ± 3.03	14.10±3.00	4.11[*]	0.008

Psychological	11.69 ± 2.78	12.70±2.81	15.43[***]	0.029
Social relationships	12.02 ± 3.03	12.42±2.77	2.39	0.005
Independence	12.75 ± 2.73	13.56±2.78	10.28[**]	0.020
Environment	12.01 ± 2.87	12.42±2.85	2.49	0.005
Spirituality	13.62 ± 3.17	13.07±3.58	3.07	0.006

[*] $p < 0.05$; [**] $p < 0.01$; [***] $p < 0.001$

Discussion

Our results suggested that the WHOQOL-HIV BREF is reliable and valid for Chinese PLWHA. The skewness and kurtosis coefficients of all items and domains were in the acceptable range (-1.00 to 1.00), which was a similar result to previous studies conducted among Taiwanese HIV-infected patients and ageing Portuguese patients with HIV.[6,44] In line with other studies,[6,44] the ceiling effect of the item measuring pain and discomfort was above the accepted threshold of 20%. It is likely that the ceiling effect is dependent on population distribution.[44] Although previous studies have not reported the floor effects of the WHOQOL-HIV BREF,[6,7,21,44] we detected floor effects for two items (social inclusion and financial resources).

Except for the spirituality domain, all domains showed satisfactory reliability. The results are consistent with other reliability studies in Malaysia, Portugal, and Ethiopia.[21,44–46] Saddki and Pereira suggested that the content and size of the spirituality domain could result in lower reliability.[21,44] Tesfaye et al. noted that the limitations of the spirituality domain in this instrument should be acknolwedged.[46] Chandra also indicated that the spirituality domain in the WHOQOL-HIV BREF may be inadequate, and he suggested that having more items in the spirituality domain on the WHOQOL-HIV could increase sensitivity in this regard.[47] We also found that the WHOQOL-HIV BREF has satisfactory test-retest reliability, which is consistent with

19

the French version.[7]

The results of the CFA suggested that the original six-domain structure could provide a generally good fit for our study data, which is consistent with other studies using the WHOQOL-HIV BREF.[9,44,46] However, the exploratory factor analysis (EFA) of the WHOQOL-HIV BREF conducted with Portuguese and Malaysian HIV-positive patients yielded a five-factor model, which contradicts the original six-domain model.[21,45] In addition to the EFA, Canavarro also conducted a CFA of the WHOQOL-HIV BREF and found that both the five-factor model and the original six-domain model fit relatively well.[45] Moreover, Peltzer's results from a multivariate logistic regression showed that four domains (psychological, independence, environment, and spirituality) were major predictors of overall QOL.[48] Some studies have suggested that the original model fit would improve if some items were modified.[45,46] The factor load of the spiritual item with its respective domain (i.e., "Spirituality" domain) was 0.11, which was much lower than others. As previously suggested, we reassigned this item to the "Psychological" domain in our study and then assessed the construct validity again. The result showed that the factor load of the spiritual item with the "Psychological" domain was 0.67, and the model fit also improved, with a CFI = 0.87, RMSEA = 0.07 (90% CI: 0.05-0.08), and AGFI = 0.89.

Concurrent validity was demonstrated by the significant correlations between two general items and the SF-36. All domains correlated significantly with self-perceived general QOL (r = 0.33-0.57, $p < 0.01$), health status (r = 0.36-0.54, $p < 0.01$), and two component summary scores of the SF-36 (r = 0.40-0.67, $p < 0.01$). The correlation

20

coefficient was comparable to that reported in the validation study of the Malay version[21] but was somewhat lower than the results of other validation studies of the WHOQOL-HIV BREF.[7,44] It was noted that the spirituality domain showed the lowest correlation with the general QOL ($r = 0.33$, $p < 0.01$) and health status ($r = 0.36$, $p < 0.01$). This finding is consistent with results found by Saddki.[21] More specifically, regarding the findings related to discriminant validity, the item measuring spirituality showed a higher correlation with the psychological domain ($r = 0.65$, $p < 0.01$) than with its initially assigned domain (i.e., spirituality; $r = 0.50$, $p < 0.01$). Canavarro also found this correlation in the European Portuguese version, and he suggested that this item should be modified or reassigned to the psychological domain.[45]

Demonstrating its known-group validity, the WHOQOL-HIV BREF discriminated between the CD4 count groups ($p < 0.05$), which is consistent with previous studies.[45,49] We also observed that the subjects with higher CD4 counts reported better QOL. This was also observed by other researchers.[47,48] However, Pereira indicated that domain scores were not significantly different across CD4 counts among ageing adults with HIV, and he implied that associations between biological markers and QOL may conflict.[44] Another result was that the physical, psychological, and independence domains discriminated relatively well between symptomatic and asymptomatic PLWHA ($p < 0.05$). A multinational pilot study also showed that the physical and independence domains discriminated better than other domains between different stages of HIV disease progression.[9] The failure of the spirituality domain to discriminate between PLWHA in 2 HIV stages may imply that although AIDS is now

a nonfatal disease, the extent of suffering from the related emotional distress remains similar at different HIV stages.[21] A previous study suggested that due to problems with understanding, the "safety and security" item could not discriminate between symptomatic and asymptomatic PLWHA.[46] This may partly explain the failure of the environment domain. The social relationships domain may face the same problems, and further studies are needed to clarify this point. Other studies have found that the WHOQOL-HIV BREF has good validity with respect to disease stage, and asymptomatic PLWHA have better QOL than do symptomatic subjects.[15,49]

There are limitations to this study that should be acknowledged. First, potential limitations are introduced by convenience sampling and self-administration of an assessment. All subjects were enrolled by convenience, and the self-administered assessment resulted in the exclusion of PLWHA with difficulty reading, which may have made the sample not representative of Chinese PLWHA. Second, various methods of administering the questionnaire such as self-administered and interviewer-administered methods should have been applied to assess its technical validity. Third, the difference of mean QOL between CD4 count subgroups are small but statistically significant. A longitudinal design might further measure the sensitivity of this instrument to changes in HIV-related indicators such as CD4 count and HIV stage; this improved sensitivity could clarify whether the difference is clinically meaningful. In addition, the percentage of missing values per item ranged from 0.2% to 2.3%. Missing values were imputed as the median score of those who answered the item. As a result, the estimated variances underestimated the variances

of the underlying distributions. Furthermore, there may be some problems in the spirituality domain, and the next step of our research should be to assess the psychometric properties again after translating and modifying this domain.

Conclusions

The WHOQOL-HIV BREF revealed good psychometric characteristics among Chinese PLWHA. These findings offer promising support for the use of the WHOQOL-HIV BREF as a measure of QOL among Chinese PLWHA and in cross-cultural comparative studies on QOL. Further studies on the spirituality domain should be conducted to ensure the effectiveness of the WHOQOL-HIV BREF.

Acknowledgments

The authors wish to thank Shijie Liang, Xia Min, and Li Wang for help with sample collection. We thank all the PLWHA participants in this study.

Competing Interests

The authors declare that they have no competing interests.

Funding

This work was supported by National Natural Science Foundation of China, grant number 71473269 and 71673301. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Author contributions

BQ designed the research. YXZ and JL participated in the data collection and analysis. YXZ wrote the manuscript. All authors read and approved the final manuscript.

Ethics approval

Ethical protocol was obtained from the Bioethics Advisory Commission of China Medical University. All of the subjects provided written informed consent and voluntarily completed self-administered questionnaires.

Data sharing statement

All data from the current study were reported in the manuscript. Participant-level data are not publicly available due to ethical and legal obligations to the participants in the study. Data are available upon request to the corresponding author and with permission of the local ethics committee.

References

1. National Health and Family Planning Commission of the People's Republic of China. 2015 China AIDS Response Progress Report. May 2015. Available: http://www.aidsdatahub.org/sites/default/files/publication/China_narrative_report_201 5.pdf. Accessed 16 January 2016.

2. NCAIDS, NCSTD, China CDC. Update on the AIDS/STD epidemic in China and main response in control and prevention in December, 2015. *Chin J AIDS STD* 2016;22(2):69. [In Chinese]

3. NCAIDS, NCSTD, China CDC. Update on the AIDS/STD epidemic in China and main response in control and prevention in February, 2016. *Chin J AIDS STD* 2016;22(4):223. [In Chinese]

4. Mutabazi-Mwesigire D, Seeley J, Martin F, Katamba A. Perceptions of quality of life among Ugandan patients living with HIV: a qualitative study. *BMC Public Health* 2014;14:343.

24

5. Mwesigire DM, Martin F, Seeley J, Katamba A. Relationship between CD4 count and quality of life over time among HIV patients in Uganda: a cohort study. *Health Qual Life Outcomes* 2015;13:144.

6. Hsiung PC, Fang CT, Wu CH, Sheng WH, Chen SC, Wang JD, et al. Validation of the WHOQOL-HIV BREF among HIV-infected patients in Taiwan. *AIDS Care* 2011; 23(8):1035-42.

7. Reychler G, Caty G, Vincent A, Billo S, Yombi JC. Validation of the French Version of the World Health Organization Quality of Life HIV Instrument. *PloS One* 2013;8(9):e73180.

8. Alonso J, Ferrer M, Gandek B, Ware JE Jr, Aaronson NK, Mosconi P, et al. Health-related quality of life associated with chronic conditions in eight countries: results from the International Quality of Life Assessment (IQOLA) Project. *Qual Life Res* 2004;13(2):283-298.

9. O'Connell KA, Skevington SM. An International Quality of Life Instrument to Assess Well-being in Adults Who are HIV-Positive: A Short Form of the WHOQOL-HIV (31 items). *AIDS Behavior* 2012;16(2):452-460.

10. Starace F, Cafaro L, Abrescia N, Chirianni A, Izzo C, Rucci P, et al. Quality of life assessment in HIV-positive persons: application and validation of the WHOQOL-HIV, Italian version. *AIDS Care* 2002;14(3):405-15.

11. Wu AW. Quality of life assessment comes of age in the era of highly active antiretroviral therapy. *AIDS* 2000;14(10):1449-51.

12. Weinfurt KP, Willke RJ, Glick HA, Freimuth WW, Schulman KA. Relationship

between CD4 Count, Viral Burden, and Quality of Life over Time in HIV-1-Infected Patients. *Med Care* 2000;38(4):404-10.

13. Skevington SM, Norweg S, Standage M; WHOQOL HIV group. Predicting quality of life for people living with HIV: international evidence from seven cultures. *AIDS Care* 2015;22(5):614-622.

14. Mutabazi-Mwesigire D, Katamba A, Martin F, Seeley J, Wu AW. Factors That Affect Quality of Life among People Living with HIV Attending an Urban Clinic in Uganda: A Cohort Study. *Plos One* 2015;10(6):e0126810.

15. Nglazi MD, West SJ, Dave JA, Levitt NS, Lambert EV. Quality of life in individuals living with HIV/AIDS attending a public sector antiretroviral service in Cape Town, South Africa. *BMC Public Health* 2014;14:676.

16. Nobre N, Pereira M, Sutinen J, Canavarro MC, Sintonen H, Roine RP. Quality of life of people living with HIV/AIDS: a cross-country comparison study of Finland and Portugal. *AIDS Care* 2016;28(7):873-7.

17. Balderson BH, Grothaus L, Harrison RG, McCoy K, Mahoney C, Catz S. Chronic illness burden and quality of life in an aging HIV population. *AIDS Care* 2013;25(4): 451-458.

18. Lubeck DP, Fries JF. Assessment of quality of life in early stage HIV-infected persons: data from the AIDS Time-Oriented Health Outcome Study (ATHOS). *Qual Life Res* 1997;6(6):494-506.

19. Peterman AH, Cella D, Mo F, McCain N. Psychometric validation of the revised Functional Assessment of Human Immunodeficiency Virus Infection (FAHI) quality

of life instrument. *Qual Life Res* 1997;6(6):572-584.

20. WHOQOL-HIV Group. Initial steps to developing the World Health Organization's Quality of Life Instrument (WHOQOL) module for international assessment in HIV/AIDS. *AIDS Care* 2003;15(3):347-357.

21. Saddki N, Noor MM, Norbanee TH, Rusli MA, Norzila Z, Zaharah S, et al. Validity and reliability of the Malay version of WHOQOL-HIV BREF in patients with HIV infection. *AIDS Care* 2009;21(10):1271-8.

22. Bowden A, Fox-Rushby JA. A systematic and critical review of the process of translation and adaptation of generic health-related quality of life measures in Africa, Asia, Eastern Europe, the Middle East, South America. *Soc Sci Med* 2003;57(7):1289-306.

23. O'Connell K, Skevington S, Saxena S; WHOQOL HIV Group. Preliminary development of the World Health Organsiation's quality of life instrument (WHOQOL-HIV): analysis of the pilot version. *Soc Sci Med* 2003;57(7):1259-75.

24. WHOQOL-HIV Group. WHOQOL-HIV for quality of life assessment among people living with HIV and AIDS: results from the field test. *AIDS Care* 2004;16(7):882-9.

25. Cai NQ, Kang J, Xu DL, Hao YT, He LY. Qualitative interview on modification of WHOQOL-HIV. *J Tra Chin Med* 2012;53(10):839-842. [In Chinese]

26. Liu WM, He LY, Wang J, Liu BY, Mark van OMMEREN, Fang JQ, et al. The introduce and usage of WHOQOL-HIV BREF instrument in Chinese. *Chin J Info Tradit Chin* 2009;16(10):1-2. [In Chinese]

27. Fu ST, Tuan YC, Yen MY, Wu WH, Huang CW, Chen WT, et al. Psychometric properties of the World Health Organization quality of life assessment-brief in methadone patients: a validation study in northern Taiwan. *Harm Reduct J* 2013;10:37.

28. Ming Z, Prybylski D, Cheng F, Airawanwat R, Zhu Q, Liu W, et al. Two-Year Prospective Cohort Study on Quality of Life Outcomes Among People Living With HIV After Initiation of Antiretroviral Therapy in Guangxi, China. *J Assoc Nurses AIDS Care* 2014;25(6):603-613.

29. Huang D, Sangthong R, Mcneil E, Chongsuvivatwong V, Zheng W, Yang X. Effects of a Phone Call Intervention to Promote Adherence to Antiretroviral Therapy and Quality of Life of HIV/AIDS Patients in Baoshan, China: A Randomized Controlled Trial. *AIDS Res Treat* 2013;2013:580974.

30. MM Shoukri, MH Asyali, A Donner. Sample size requirements for the design of reliability study: Review and new results. *Statistical Methods in Medical Research* 2004;13(4):251-271.

31. CDC. 1993 revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. *MMWR Recomm Rep* 1992;41(RR-17):1-19.

32. CDC. Comparison of the revised World Health Organization and CDC surveillance case definitions and staging systems for HIV Infection. *MMWR Recomm Rep* 2008;57(RR10):10-11.

33. Ware J, Sherbourne SD. The MOS 36-item short form health survey (SF-36). 1.

Conceptual frame-work and item selection. *Medical Care* 1992;30(6):473-481.

34. Meng YJ, Li NX, Liu CJ, Chen JH, Song YC, Qian ZS. Quality of life and hostile mentality trend of patients with HIV/AIDS in China. *Public Health* 2008;122(4):404-11.

35. Bing EG, Hays RD, Jacobson LP, Chen B, Gange SJ, Kass NE, et al. Health-related quality of life among people with HIV disease: Results from the Multicenter AIDS Cohort Study. *Qual Life Res* 2000;9(1):55-63.

36. Liu C, Ostrow D, Detels R, Hu Z, Johnson L, Kingsley L, et al. Impacts of HIV infection and HAART use on quality of life. *Quality of Life Research* 2006;15(6):941-949.

37. Zhu Y X, Li T, Fan S R, Liu XP, Liang YH, Liu P. Health-related quality of life as measured with the Short-Form 36 (SF-36) questionnaire in patients with recurrent vulvovaginal candidiasis. *Health Qual Life Outcomes* 2016;14(1):1-6.

38. Hays RD, Sherbourne CD, Mazel RM. The RAND 36-Item Health Survey 1.0. *Health Economics* 1993;2(3):217-27.

39. Holmes W, Shea J. Performance of a new, HIV/AIDS-targeted quality of life (HAT-QoL) instrument in asymptomatic seropositive individuals. *Qual Life Res* 1997;6(6):561-571.

40. van Lummel RC, algaard S, Hobert MA, Maetzler W, van Dieën JH, Galindo-Garre F, et al. Intra-Rater, Inter-Rater and Test-Retest Reliability of an Instrumented Timed Up and Go (iTUG) Test in Patients with Parkinson's Disease. *Plos One* 2016;11(3):e0151881.

41. Byrne BM. Structural equation modeling with Lisrel, Prelis, and Simplis. Basic concepts, applications, and programming. *Structural Equation Modeling A Multidisciplinary Journal* 1998;7(4):640-643.

42. Yekaninejad MS, Pakpour A H, Tadakamadla J, Kumar S, Mosavi SH, Fridlund B, et al. Oral-health-related quality of life in patients with cancer: cultural adaptation and the psychometric testing of the Persian version of EORTC QLQ-OH17. *Support Care Cancer* 2015;23(5):1215-24.

43. Jiang XH, Shen ZZ, Zhang NN, Liao HX, Xu HY. Research on reliability and validity of questionnaire. *Mod Prev Med* 2010;37(3):429-431. [In Chinese]

44. Pereira M, Martins A, Alves S, Canavarro MC. Assessing quality of life in middle-aged and older adults with HIV: psychometric testing of the WHOQOL-HIV-Bref. *Qual Life Res* 2014;23(9):2473-9.

45. Canavarro MC, Pereira M. Factor structure and psychometric properties of the European Portuguese version of a questionnaire to assess quality of life in HIV-infected adults: the WHOQOL-HIV-Bref. *AIDS Care* 2012;24(6):799-807.

46. Tesfaye M, Olsen MF, Medhin G, Friis H, Hanlon C, Holm L. Adaptation and validation of the short version WHOQOL-HIV in Ethiopia. *Int J Ment Health Syst* 2016;10:29.

47. Chandra PS, Gandhi C, Satishchandra P, Kamat A, Desai A, Ravi V, et al. Quality of life in HIV subtype C infection among asymptomatic subjects and its association with CD4 counts and viral loads-a study from South India. *Qual Life Res*

2006;15(10):1597-1605.

48. Peltzer K, Phaswanamafuya N. Health-related quality of life in a sample of HIV-infected South Africans. *Afr J AIDS Res* 2008;7(2):209-218.

49. Tran BX. Quality of life outcomes of antiretroviral treatment for HIV/AIDS patients in Vietnam. *Plos One* 2012;7(7):e41062.

Fig 1. The structure of the Chinese version of the WHOQOL-HIV BREF based on confirmatory factor analysis.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
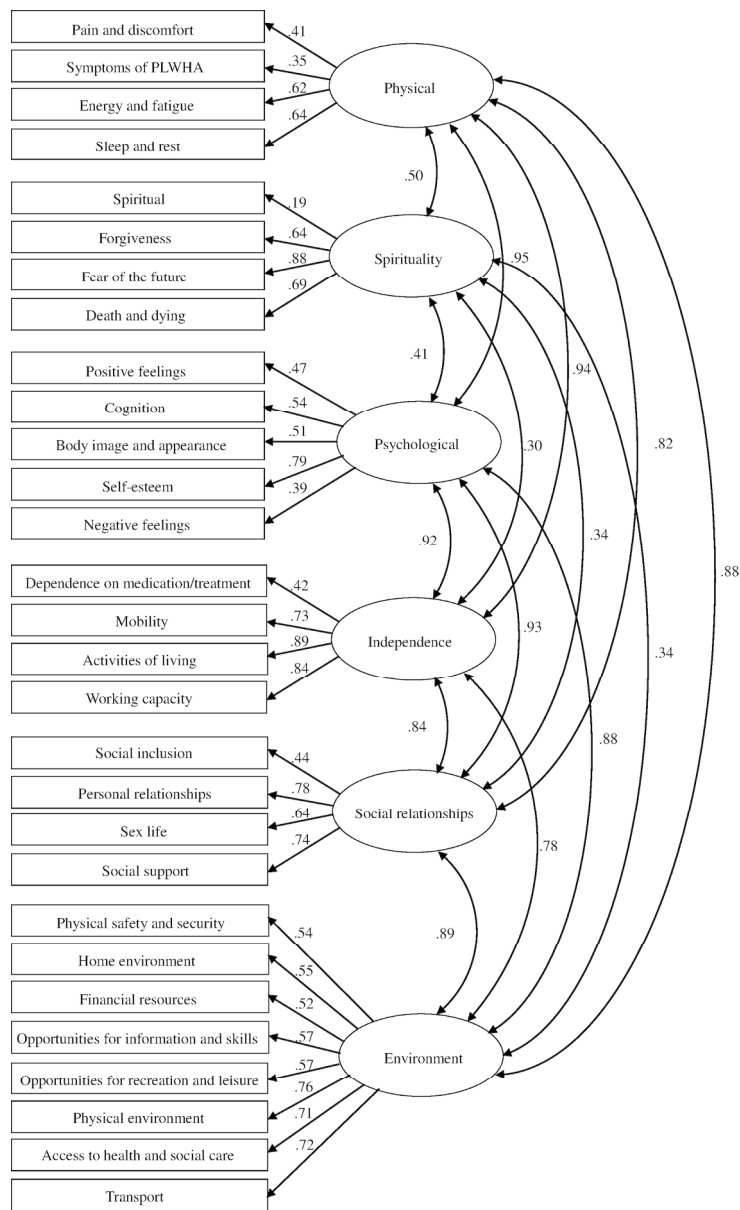

Fig 1. The structure of the Chinese version of the WHOQOL-HIV BREF based on confirmatory factor analysis.

134x222mm (300 x 300 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2, 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4, 5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	6, 7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6, 7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7, 8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7, 8
Bias	9	Describe any efforts to address potential sources of bias	*6*

Study size	10	Explain how the study size was arrived at	6, 7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8, 9
		(*b*) Describe any methods used to examine subgroups and interactions	8, 9
		(*c*) Explain how missing data were addressed	8
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	6, 7
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6, 9
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9, 10
		(b) Indicate number of participants with missing data for each variable of interest	6
Outcome data	15*	Report numbers of outcome events or summary measures	9-19
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	14-19
		(*b*) Report category boundaries when continuous variables were categorized	9-19

		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	19, 20, 21, 22
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	22
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19, 20, 21, 22
Generalisability	21	Discuss the generalisability (external validity) of the study results	22
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	22

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.