SYSTEMATIC REVIEW

Investigating quality of life instrument measurement properties for adults with active venous leg ulcers: A systematic review

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Abstract

The primary objective of this systematic review was to identify which quality of life instruments have been applied in published studies of patients with active venous leg ulcers. Our secondary objective was to map the measurement properties of each identified quality of life instrument and to inform future recommendations for clinical practice and research. We searched CINAHL, Ovid Medline, Ovid Emcare and ProQuest to identify studies published from 1 January 2000 to 31 July 2021. Eleven studies that utilised quality of life instruments in adults with active venous leg ulcers met the inclusion criteria. Thirteen quality of life instruments were identified as some studies utilised both generic and condition-specific quality of life instruments. Six out of nine (6/9) instruments were rated 'very good' of methodological quality on internal consistency; 1/7 studies rated 'adequate' on reliability; 2/4 rated 'adequate' on content validity; 3/6 studies rated 'adequate' on structural validity; 5/6 rated 'adequate' on hypotheses testing for construct and 2/6 studies rated 'adequate' on responsiveness. There is limited evidence of measurement properties of quality of life instruments for people with active venous leg ulcers. The Venous Leg Ulcer Quality of Life Questionnaire (VLU-QoL) could be provisionally recommended for use although from our review it is clear further studies to assess VLU-QoL measurement properties are needed to inform future recommendations for clinical practice and research.

KEYWORDS
COSMIN checklists, measurement properties, quality of life, quality of life measures, venous leg ulcers

1 | INTRODUCTION

Venous leg ulcers (VLUs) are the most common chronic lower limb wounds,[1] which accounts for almost 80% of all lower-extremity wounds found in the community.[2] VLUs are caused by venous hypertension that result from chronic venous insufficiency and impaired calf muscle.[3] Possible implicating factors for non-healed VLUs includes increased ulcer size, prolonged ulcer duration, previous history of ulceration, venous abnormalities, reduced mobility, lack of appropriate compression, malnutrition and older ages.[4] The severity of VLUs is classified by the CEAP (Clinical, Etiology, Anatomy and Pathophysiology) classification on a spectrum of severity from C0 to C6 (C0 showing no visible or palpable signs of venous disease and C6 being active venous ulcer).[5] The lifetime prevalence of VLUs in the total western population is estimated to be up to 1%.[4] It is also estimated that the prevalence of people aged over 65 years of age is higher at 3%–4%.[4]

Due to protracted healing times, living with venous ulceration have been shown to have a negative impact on patient's quality of life (QoL),[6] which represent physical, psychological, social and economic implications.[7,8] Patients often experience pain and have exudate with bad odour. They may have pyrexia, malaise and foot oedema due to local inflammation.[7] VLUs may negatively affect patients' self-esteem and lead to body-image dissatisfaction.[9] Psychological issues, such as depression, social isolation, fear and frustration, combined with physical symptoms have a negative impact on patient's quality of life.[8] Chronic VLUs, which may take years to heal, have a significant financial burden on patients and the healthcare systems.[6,7] Estimated average weekly costs between VLUs in usual and optimal care have been reported as AU$214.61 and AU$294.72 per patient, respectively.[6]

Compression therapy is recommended by the Australian and New Zealand clinical practice guidelines for prevention and management of VLUs.[10] Compression therapy is usually applied by trained health professionals to reduce hydrostatic pressure and improve blood flow.[11] However, even with compression application, many VLUs remain unhealed due to lack of effective compression therapy[12] or non-adherence to compression therapy.[13] Patient adherence to compression therapy can be affected by pain, compression discomfort[14] and patients' inadequate understanding of consequences of not wearing compression.[14]

Measuring QoL can assist healthcare professionals to assess the perceived health status of VLUs patients.[15] Assessing QoL can also help to develop a comprehensive care plan considering the patient's physical, psychological and social needs.[16] A comprehensive care plan will also help to reduce the economic burden of hospitalisation, and the cost of wound care products and medication.[17,18] Many different instruments have been used to assess QoL in VLUs studies including both generic and condition-specific instruments.[7] Generic QoL instruments can be utilised across wide range of patient population groups; and the condition-specific QoL instruments are designed to assess QoL in patients with a particular disease or condition.[19] Before choosing a QoL instrument, healthcare professionals should consider the measurement properties of the target QoL instrument including

reliability, validity and responsiveness.[20] An appropriate QoL instruments should be validated in the target population and should be able to reflect the outcome accurately. An appropriate instrument should also have the ability to detect change over time.[20] To date, there were no QoL instruments that were highly recommended for use in studies of adult patients with active VLUs. The primary objective of this systematic review was to identify which quality of life instruments have been applied in published VLUs studies of patients with active VLUs. Our secondary objective was to map the measurement properties of each identified quality of life instrument and to inform future recommendations for clinical practice and research.

1.1 | Review questions

- Which instruments assess the impact of VLUs on QoL of adults with active VLUs?
- What are the measurement properties of identified QoL instruments?
- Which QoL instruments are suitable for an assessment of the impact of VLUs on QoL of adults with active VLUs in clinical practice?

2 | METHODS

This review was conducted in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[21] The protocol of this systematic review was published[22] and has been registered at the International Prospective Register of Systematic Reviews (PROSPERO) (CRD42021251734).

2.1 | Eligibility criteria

2.1.1 | Inclusion criteria

Quantitative studies that report at least one measurement property of QoL in adult participants with active VLUs (as defined by the authors). Both generic and VLU specific instruments were included. We included studies in English version that were published between 1 January 2000 and 31 July 2021.

2.1.2 | Exclusion criteria

We excluded: studies that had been published prior to 2000, studies that recruited participants with ulcers from other aetiologies, such as diabetic ulcers, arterial ulcers or infected ulcers, studies in asymptomatic participants or participants with healed VLUs. We also excluded unpublished studies, letters to the editor, abstract-only QoL intervention reports that did not report measurement properties of QoL instruments, systematic or scoping reviews and qualitative studies.

2.2 | Information sources

We searched the following electronic databases, Ovid Medline, CINAHL, Ovid Emcare and ProQuest from 1 January 2000 to 31 July 2021.

2.3 | Search strategy

A preliminary search was conducted following the search strategy listed in the protocol,[22] which included the keywords and words variants of 'venous leg ulcers', 'quality of life' and 'instruments'. However, many of the extracted papers did not report the measurement properties of QoL instruments. A subject librarian was consulted to refine the search strategy, which was updated with additional keywords and variants of measurement properties (Appendix).

2.4 | Selection process

Retrieved papers were imported to Covidence (https://www.covidence.org/) for data selection. All retrieved papers were independently screened by two review authors (Shiwen Liu and Yunjing Qiu) following the inclusion/exclusion criteria. Disagreements were resolved via consensus and the third review author (Victoria Team) was consulted.

2.5 | Data collection process and data items

Data, as outlined in Table 1 were extracted by two review authors (Shiwen Liu and Yunjing Qiu): general study information, participant information, methodology information and instrument information.

2.6 | Assessment of methodological quality

Two review authors (Shiwen Liu and Yunjing Qiu) independently assessed the methodological quality of included studies. The COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) Risk of Bias checklist were applied to assess the methodological quality of retrieved studies.[23] Disagreements between two review authors were resolved by consensus or third review author (Victoria Team) was consulted.

2.7 | Synthesis methods

The extracted data of this review were reported in narrative and tabular synthesis. The measurement properties of each QoL instrument were assessed by a 'criteria for good measurement properties' generated from COSMIN guidelines.[20] Another adapted criteria from a previous review study[24] was adopted to evaluate structural validity that was not included in the 'criteria for good measurement properties'. Initially, we planned to conduct a meta-analysis of Cronbach's α,

TABLE 1 Data extraction information

General information	Authors
	Publication year
	Country location
Methodology information	Study setting
	Study design
	Sample size
	Inclusion/exclusion criteria
Instrument information	Name of QoL instruments and domains
	Item numbers of QoL instruments
	Type of questions
	Who completes instrument?
	Timing to complete a QoL instruments
	Original Language
	Number of translations
	Ease of administration
	Cost of instrument
	Access of instrument
	Internal consistency
	Reliability
	Measurement error
	Content validity
	Construct validity
	Criterion validity
	Responsiveness.
Participant's information	Mean age and gender (%male)
	Duration of active VLU
	Wound size
	Wound duration
	Treatment

intraclass correlation coefficient (ICC) and Pearson correlation coefficient. We were unable to perform a meta-analysis in this review as planned because some studies did not report on the three types of measurement properties. Other studies used different methods for reporting the same measurement properties; and the results were not able to be pooled in meta-analysis.

2.8 | Certainty assessment

A modified version of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach[20] were adopted in this review to evaluate the quality of each instrument as a whole.

3 | CHANGES TO THE PROTOCOL

The review adopted extra criteria to assess structural validity as COSMIN guidelines did not contain the criteria for exploratory factor analysis. The criteria for structural validity adopted from a recent

systematic review on the measurement properties of QoL instruments for eczema patients.[24] The QoL physical score, social function score and mental health score were not reported in this review as most studies reported the total QoL score without reporting the scores of separate dimensions.

4 | RESULTS

4.1 | Study selection

In total, 1102 studies were retrieved from the electronic database searching and were imported to Covidence for screening. As shown in Figures 1, 225 duplicates and 791 studies that did not meet the inclusion criteria were removed at the first screening step. Eighty-six full-text studies were assessed for eligibility and 75 were removed due to different reasons showed in Figure 1. An additional pilot study[25] identified from citation searching was excluded as no further formal study was published. Therefore, 11 studies in total were included in this systematic review.

4.2 | Study characteristics

An overview of characteristics of included studies and study participants are presented in Tables 2 and 3. Thirteen QoL instruments were evaluated in this review. We identified five studies that reported generic QoL instruments, these included Nottingham Health Profile (NHP),[36] the Client Generated Index (CGI),[35] the EuroQoL Five

Dimensions (EQ-5D),[27,33] 12-item Short-Form Health Survey (SF-12)[33] and 36-item Short Form Health Survey (SF-36).[27] Eight condition-specific QoL instruments were identified: Charing Cross Venous Ulcer Questionnaire (CCVUQ),[27,28] Charing Cross Venous Ulcer Questionnaire-Brazil (CCVUQ-Brazil),[29] Chinese version of the Charing Cross Venous Ulcer Questionnaire (CCVUQ-C),[30] the Venous leg ulcer quality of life questionnaire (VLU-QoL),[31] the Venous leg ulcer quality of life questionnaire- Brazil (VLU-QoL-Br),[32] Hyland Questionnaire,[33] the Sheffield Preference-based Venous Ulcer questionnaire (SPVU-5D)[34] and Venous Insufficiency Epidemiological and Economic Study Quality of Life (VEINES-QOL).[26]

There were 6 out of 11 studies that were conducted in the United Kingdom.[26,28,31,33,34,36] The remainder were conducted in Australia,[35] New Zealand,[27] Brazil[29,32] and Hong Kong (SAR).[30] Five studies were conducted in community settings.[27,28,31,35,36] The sample size of included studies varied from 29[35] to 454 patients.[26] Studies were mainly published between 2000 and 2019. The mean of age of included participants ranged from 61.39[29] to 76 years.[28] Even though all included studies were written in English, there were three QoL instruments presented in Chinese[30] and Brazilian Portuguese.[29,32] In the studies that provided treatment information, compression therapy was the main treatment intervention for patients with VLUs.

4.3 | Methodological quality of studies

The methodology quality of included studies with measurement properties is presented in Table 4. Internal consistency and reliability were the most assessed measurement properties.
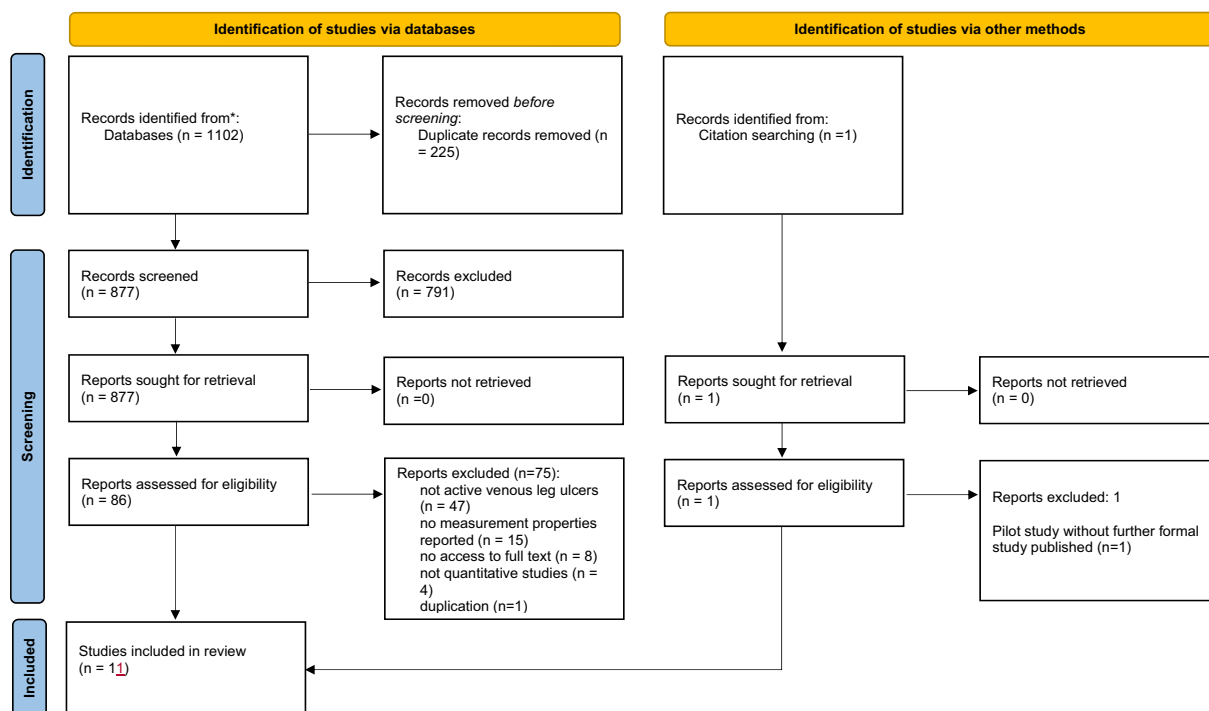

FIGURE 1 PRISMA flow diagram. From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ*. 2021;372:71. doi: 10.1136/bmj.n71 [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 Characteristics of included studies

Instruments assessed	Author and year	Type of instrument(s)	Country and language	Study design	Setting/Context	Timing of assessment	Outcomes of interest
VEINES-QOL[26]	Bland et al. (2015)	Condition-specific instrument	UK: English	RCT	N/A	Baseline; 2 weeks and 4 months	Hypotheses testing for construct, responsiveness, internal consistency, reliability, structural validity and criterion validity
CCVUQ[27,28]	Smith et al. (2000)[28] Jull et al. (2010)[27]	Condition-specific instrument	UK: English[28] New Zealand: English[27]	Instrument development and validation study[28] RCT[27]	community-based ulcer clinic or the local regional vascular unit[28] Community-based district nursing services[27]	Baseline, 6 weeks and 12 weeks[28] Baseline; 12 weeks[27]	Responsiveness[27,28] (Internal consistency, reliability, content validity, structural validity, criterion validity and hypotheses testing for construct)[28]
CCVUQ-Brazil[29]	Amaral et al. (2019)	Condition-specific instrument	Brazil: Brazilian Portuguese	Non-RCT, observational study	Public health facilities	Baseline; 30 min	Internal consistency and reliability
CCVUQ-C[30]	Wong et al. (2006)	Condition-specific instrument	China-Hong Kong: Chinese	Prospective descriptive study	Wound clinic in a regional hospital	Baseline; 6 weeks	Criterion validity, hypotheses testing for construct, internal consistency, structural validity and reliability
VLU-QoL[31]	Hareendran et al. (2007)	Condition-specific instrument	UK: English	Instrument development and validation study	Community and hospital outpatient leg ulcer clinics	Baseline; 48-72 h later; 8 weeks	Reliability, hypotheses testing for construct, responsiveness, internal consistency, content validity and structural validity
VLU-QoL-Br[32]	Araújo et al. (2014)	Condition-specific instrument	Brazil: Brazilian Portuguese	Non-RCT	Chronic ulcer outpatient clinic	Baseline; up to 30 days; up to 60 days	Internal consistency, reliability and structural validity
Hyland questionnaire[33]	Iglesias et al. (2005)	Condition-specific instrument	UK: English	RCT	N/A	Baseline; every 3 months of the 1st year	Internal consistency and structural validity
SPVU-5D[34]	Palfreyman (2008)	Condition-specific instrument	UK: English	Instrument development and validation study	Tissue viability service	Baseline; 3 weeks but did not report result	Internal consistency and content validity
CGi[35]	Griffiths et al. (2000)	Generic instrument	Australia: English	Instrument development and validation study	Community health service, local home nursing service, retirement village	Baseline; 5 weeks	Reliability, criterion validity, hypotheses testing for construct, content validity
SF-12[33]	Iglesias et al. (2005)	Generic instrument	UK: English	RCT	N/A	Baseline; every 3 months of the 1st year	Responsiveness
SF-36[27]	Jull et al. (2010)	Generic instrument	New Zealand: English	RCT	Community-based district nursing services	Baseline and 12 weeks	Responsiveness

TABLE 2 (Continued)

Instruments assessed	Author and year	Type of instrument(s)	Country and language	Study design	Setting/Context	Timing of assessment	Outcomes of interest
EQ-5D[27,33]	Iglesias et al. (2005)[33] Jull et al. (2010)[27]	Generic instrument	UK: English[33]; New Zealand: English[27]	RCT	N/A[33]; Community-based district nursing services[27]	Baseline and every 3 months of the 1st year[33]; Baseline and 12 weeks[27]	Responsiveness[27,33]
NHP[36]	Frank and Moffatt (2001)	Generic instrument	UK: English	Non-RCT	Community leg ulcer clinics or patients' home	Baseline; 12 weeks	Internal consistency, hypotheses testing for construct, floor/ceiling effect and responsiveness

Abbreviations: CCVUQ, Charing Cross Venous Ulcer Questionnaire; CGI, Client Generated Index; EQ-5D, EuroQol-Five Dimensions Questionnaire; NHP, Nottingham Health Profile; SF-12, 12-item Short-Form Health Survey; SF-36, 36-item Short Form Health Survey; SPVU-5D, Sheffield Preference-based Venous Ulcer Questionnaire; VEINES-QOL, VEnous INsufficiency Epidemiological and Economic Study-Quality of Life; VLU-QoL, Venous Leg Ulcer Quality of Life Questionnaire.

4.3.1 | Internal consistency

Nine out of 11 included studies reported internal consistency of the QoL instrument.[26,28–34,36] One study[34] was rated 'doubtful' and two studies[26,28] were rated 'inadequate' on internal consistency. The main reason for low quality ratings was not calculating internal consistency statistic for each unidimensional (sub)scale separately.

4.3.2 | Reliability

There were seven studies reporting reliability,[26,28–32,35] There were two studies reporting inadequate reliability.[28,29] Low quality ratings were caused by inappropriate time interval between two administrations of QoL instruments[29–31,35] or inappropriate statistical methods.[28]

4.3.3 | Content validity

Four[28,31,34,35] out of 11 studies assessed the content validity and two[28,31] of them were rated 'adequate'. The other two[34,35] were rated 'doubtful' because neither of these two studies reported the comprehensiveness and comprehensibility of instruments from both patients and professionals' aspects.

4.3.4 | Structural validity

Five studies[26,28,30,32,33] reported structural validity. Three of them[26,30,33] were rated as 'adequate' and the other two[28,32] were rated as' inadequate'. The reason for inadequate ratings was inadequate sample size.

4.3.5 | Hypotheses testing for construct validity

Six studies[26,28,30,31,35,36] assessed hypotheses testing for construct validity. Five studies[26,28,30,31,35] were rated 'adequate' and one[36] were rated as 'doubtful'. The fair or lower rating were caused by inappropriate statistical method.

4.3.6 | Responsiveness

Six studies reported responsiveness for eight instruments.[26–28,31,33,36] Of these six studies reporting responsiveness, two studies[26,31] were rated as 'adequate' and two[27,33] were rated as 'doubtful' due to the statistical methods of effect size (ES) or standardised response mean (SRM) without an explicit hypotheses for the expected magnitude. The remaining two studies[28,36] were rated 'inadequate' due to the use of inappropriate statistical methods, such as paired t-test.

4.3.7 | Criterion validity

Five studies reported criterion validity, of which three studies[28,31,35] compared their QoL instruments with SF-36. One study[26] measured

TABLE 3 Participant's information

Author	Instrument(s) assessed	Participants	Age[a] (years)	Gender (%male)	VLUs duration[b]	Wound size[b] (cm²)	Treatment
Franks and Moffatt[36]	NHP	383	74	140 (36.6)	12 months	<10 cm²: 55.7% ≥10 cm²: 44.3%	High compression therapy
Amaral et al.[29]	CCVUQ-Brazil	112	61.39 (±11.86)	56 (50%)	60 months		
Wong et al.[30]	CCVUQ-C	100	70	70 (70%)	48mths	8.4	
Hareendran et al.[31]	VLU-QoL	P2: 124 P3: 120			P2:40.8 months P3: 36.9 months	P2: 32.1 mm of diameter P3: 38.9 mm of diameter	Compression bandaging
Araújo et al.[32]	VLU-QoL-Br	82	67.3 (±13.9)	26 (32%)	162 months	8	
Griffiths et al.[35]	CGI	29					
Iglesias et al.[33]	EQ-5D, SF-12 and Hyland questionnaire	387	71.6 (±13.21)	159 (41%)	3 years	3.8	Compression therapy
Jull et al.[27]	SF-36, EQ-5D and CCVUQ	360 with VLUs	67.7	176 (48.9)	18 weeks	2.6	Manuka honey-impregnated calcium alginate dressings in addition to compression bandaging; usual care
Palfreyman[34]	SPVU-5D	152 with VLUs	66.6		≥12 months: 36% Newly diagnosed ulcer: 32%		
Bland et al.[26]	VEINES-QOL	454 with VLUs	68.6	230 (50.7%)	4 months	3.9	Two-layer compression hosiery; four-layer bandage system
Smith et al.[28]	CCVUQ	98 with active VLUs	76	34%	≥2 weeks	≥1 cm²	

[a]represent mean.
[b]represent median (interquartile range).

TABLE 4 Methodological quality of the included studies per measurement property

| Instrument | Reliability | | | Validity | | | | | Responsiveness |
	Internal consistency	Reliability	Measurement error	Content validity	Structural validity	Hypotheses testing for construct	Cross-cultural validity	Criterion validity	
NHP[36]	V					D			I
CGI[35]		D		D		A		NR	NR
EQ-5D[27,33]									D[28] D[27]
SF-12[33]									D
SF-36[27]									D
CCVUQ-Brazil[29]	V	I							
CCVUQ-C[30]	V	D			A	A		NR	
VLU-QoL-Br[32]	V	A			I				
Hyland[33]	V				A				NR
SPVU-5D[34]	D			D					
CCVUQ[27,28]	I[28]	I[28]		A[28]	I[28]	A[28]		NR[28]	I[28] D[27]
VEINES-QOL[26]	I	V			A	A		NR	A
VLU-QoL[31]	V	D		A	I	A			A

Abbreviations: A, adequate; D, doubtful; I, inadequate; NR, not rated; V, very good.

its correlation with SF-12 and one[33] used the Chinese version of the Frenchay Activities Index (FAI-C), the Brief Pain Inventory (BPI-C) and SF-12 to determine the criterion validity. However, none of those instruments were considered as a 'gold standard' or it was hard to decide a 'gold standard' for QoL instruments. Therefore, the methodological qualities of criterion validity reported in the included studies were not assessed.

We were unable to assess the measurement error and cross-cultural validity due to lack of eligible studies.

4.4 | Results of individual studies

All results on the measurement properties of included QoL instruments were shown in Tables 5 and 6. All measurement properties were assessed by a 'criteria for good measurement properties' generated from COSMIN guidelines except for floor and ceiling effect because there was no rating standard for floor and ceiling effect in COSMIN guidelines. The rating of the measurement properties of QoL instruments were also presented in Tables 5 and 6. Levels of the quality of evidence evaluated by the modified GRADE were presented in Table 7.

4.4.1 | Nottingham Health Profile

One study described the measurement properties of NHP.[36] NHP is a generic instrument for measurement of QoL. This instrument that produces binary responses (yes or no) and contains 38 items and six domains including energy, bodily pain, emotion, sleep, social isolation and physical mobility. This instrument was completed by either the 383 participants or the interviewers if the participants chose the option of interviewer administration. Internal consistency was examined by the Cronbach's α score. There was high quality evidence that the reliability of NHP is indeterminate. NHP also showed low evidence for indeterminate responsiveness. The ES and SRM were used to evaluate the responsiveness of NHP after 12 weeks of treatment. The positive SRM was considered as an improvement in status. The evidence of the hypotheses testing for construct validity was rated as low. This study also reported a large floor effect, particularly in social isolation, emotional status and energy.

4.4.2 | Client Generated Index

The CGI is a generic QoL instruments that contains six steps. An instrument development and validation study[35] published in Australia was conducted to assess the measurement properties of CGI. This instrument was reported to be completed by healthcare providers. CGI was generated by modifying an instrument used by Ruta[37] in clinical settings.[35] Content validity reported a very low level of inconsistent content validity. However, there was very low evidence for this indeterminate reliability due to the small sample size and lack of ICC.

The study compared the initial CGI with the SF-36 and the CGI correlated with bodily pain, mental health, physical function and role emotional. To test the construct validity, the CGI was correlated to pain as a clinical marker. The value of r showed very low evidence of hypotheses testing for indeterminate construct.

4.4.3 | EuroQoL Five Dimensions

EQ-5D is a generic instrument with five domains, including mobility, self-care, ability to undertake usual activities, pain and anxiety/depression.[33] Two studies presented information on the EQ-5D instrument.[27,33] This instrument was completed by participants.[33] ES[33] and SRM[27] were applied for assessing responsiveness of EQ-5D. The results of responsiveness were reported inconsistently as they were using different statistical methods, thus the evidence of responsiveness was not evaluated. The results and ratings of responsiveness reported separately.

4.4.4 | 12-item Short-Form Health Survey

SF-12 is a generic QoL instrument that consists of eight dimensions, including general health, physical functioning, role physical, role emotional, bodily pain, mental health, vitality and social functioning. The ES and SRM showed that SF-12 were responsive to changes in HRQoL after ulcer healing. SF-12 had the highest response rate in the study and ranges from 93% at baseline to 61% at 12 months. However, the hypotheses for responsiveness were not stated, and the magnitude of ES and SRM was not provided. Therefore, the responsiveness was considered indeterminate with a very low level of evidence.

4.4.5 | 36-item Short Form Health Survey

SF-36 is a 36-item generic QoL instrument with eight domains, including physical functioning, role limitations due to physical problems, bodily pain, general health, energy/vitality, social functioning, role limitations due to emotional, problems and mental health. One study reported the measurement properties of SF-36.[27] SRM was used to assess responsiveness; and the results were trivial to small (SRM: −0.01 to 0.47). However, the hypotheses for responsiveness were not stated and, thus, the responsiveness was considered indeterminate with a low level of evidence.

4.4.6 | Charing Cross Venous Ulcer Questionnaire

This 20-item condition-specific QoL instrument with Likert scale[29,30] contains four dimensions: social function, domestic activities, emotional status and cosmesis.[27] One study[30] reported that this instrument required 10 min to complete for elderly patients. Charing Cross

TABLE 5 Results and rating of measurement properties: Generic QoL instruments

Instrument	Reliability		Validity							Responsiveness
	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Cross-cultural validity	Criterion validity	
					Structural validity	Hypotheses testing for construct				
NHP[36]	(?) Cronbach's α 0.63–0.81	X	X	X	X	(?) Physical mobility with age d: 0.69, mobility d: 1.3, ulcer size d: 0.35, ulcer duration d: 0.41		X	X	(?) SRM: healed: 0.14–0.68; unhealed: 0.15–0.37
CGI[35]	X	(NR) r = 0.53 (The Pearson's correlation coefficient)	X	(±)	X	(?) The correlation of the CGI with pain as a clinical marker r = 0.54 (p = 0.001) SF-36: r = 0.11–0.48		X	NR SF-36: r = 0.11–0.48	X
EQ-5D[27,33]	X	X	X	X	X	X		X	X	(±) (Unhealed ulcers: ES: 0.1; healed ulcers: ES:0.5 Small to moderate)[33] (Unhealed ulcer: SRM:0.10–0.31; healed ulcer: 0.13–0.31. trivial to small)[27]
SF-12[33]	X	X	X	X	X	X		X	X	(?) Unhealed ulcers: ES: −0.1 to −0.3; healed ulcers: ES: 0.1 to −0.5
SF-36[27]	X	X	X	X	X	X		X	X	(?) Unhealed: SRM: −0.01 to 0.24; healed: SRM: −0.07 to 0.47 The SRMs were trivial to small

Abbreviations: +, sufficient; −, insufficient; ?, indeterminate; ±, inconsistent; NR, not rated; X, not reported.

TABLE 6 Results and rating of measurement properties: condition-specific QoL instruments

Instrument	Reliability			Validity						Responsiveness
	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Criterion validity	
					Structural validity	Hypotheses testing for construct	Cross-cultural validity		
CCVUQ-Brazil[29]	(?) Cronbach's α for the entire instrument was 0.92; social interaction: 0.774; domestic activities: 0.824; aesthetics: 0.815; emotional state: 0.773.	(+) ICC: 0.897–0.963	X	X	X	X	X	X	X
CCVUQ-C[30]	(+) Cronbach's α for the entire instrument was 0.95; social interaction division: 0.92; domestic activities division: 0.92; cosmesis division 0.94; emotional status division: 0.90.	(+) ICC: 0.94	X	(NR) Content validity index: 0.82	(+) Four-factor, confirmatory factor analysis Factor 1: Social interaction Factor 2: Domestic activities Factor 3: Cosmesis Factor 4: Emotional status CFI: 0.96	(+) SF-12 physical health $r = -0.42$, $p < 0.001$; SF-12 mental health $r = -0.65$, $p < 0.001$; social interaction with the physical health of SF-12 $r = -0.63$, $p < 0.001$; domestic with the physical health of SF-12: $r = -0.43$, $p < 0.001$	X	(NR) Correlation with the FAI-C and BPI-C: 0.62 and 0.76, $p < 0.001$	X
VLU-QoL-Br[32]	(?) Cronbach's α for the entire instrument was 0.94, 0.91 (activities); 0.91 (psychological) and 0.88 (symptoms)	(+) Assessment within 30 days: n = 19; ICC = 0.90. Assessment within 60 days: n = 32; ICC = 0.78.	X	X	(+) Three-factor (52%) The CFA showed significant standardised coefficients >0.43 ($p < 0.01$) for each dimension of the construct	X	X	X	X
VEINES-QOL[26]	(?) Cronbach's α = 0.88	(+) ICC = 0.80 Weighted Kappa statistic = 0.42–0.73	X	X	(?) Three-factor Factor 1: Usual activities. Factor 2: VEINES-Sym symptom Factor 3: Feelings	(+) Convergent validity: SF-12 physical: $r = 0.58$ SF-12 mental: $r = 0.58$ Divergent validity: Age: $r = 0.25$	X	(NR) The correlation of physical component with SF-12 is 0.58; the correlation of mental component with SF-36 is 0.43	(?) Responsiveness coefficient ranges from 0.42–0.50

TABLE 6 (Continued)

Instrument	Reliability			Validity					Responsiveness
	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Criterion validity	
					Structural validity	Hypotheses testing for construct	Cross-cultural validity		
Hyland questionnaire[33]	(?) Factor 1: Cronbach's α = 0.82 Factor 2: Cronbach's α = 0.79	X	X	X	(−) Two-factor (34.15%) Factor 1: Practical Factor 2: Emotional	X	X	X	(NR) Ambiguous responsiveness
SPVU-5D[34]	(?) Cronbach's α = 0.934	X	X	(±)	X	X	X	X	X
VLU-QoL[31]	(?) The internal consistency reliability of each of the three domains was found to be high (Cronbach's a >0.8)	(+) ICC: Activities 0.85, Psychological 0.83, Symptom distress 0.86	X	(+)	(+) Three-factor: (55%) Factor 1: Activity limitation Factor 2: Psychological effects Factor 3: Symptoms distress	(+) Convergent validity: SF-36 Physical: r = −0.642, p <0.01 (activities) SF-36 Mental health: r = −0.617(psychological) r = −0.171 to −0.4759 (symptoms) Discriminant validity: the diameter of the largest ulcer: (r_s = 0.23, p <0.05)	X	X	(?) At follow-up, improvement: 25 (36%) no change: 36 (52%) deterioration: eight (12%)
CCVUQ[27,28]	(?) (Cronbach's α = 0.93)[28]	(?) (Test-retest analysis: r = 0.84)[28]	X	(±)[28]	(?) Four-factor Factor 1: Social function Factor 2: Domestic activities Factor 3: Cosmesis Factor 4: Emotional status.	(?) Convergent validity: (Correlation with all eight domains of the SF-36 general health measure: −0.522 to −0. 706)[28]	X	(NR) Correlation with all eight domains of the SF-36 general health measure: −0.522 to −0. 706.[28]	(±) (The SRMs: moderate to large in healed group; small in the unhealed group)[27] (The mean score calculated for the questionnaire had decreased by 10% (p = 0.022), and at 12 weeks, it decreased by 54% (p = 0.005))[28]

Abbreviations: +, sufficient; −, insufficient; ?, indeterminate; ±, inconsistent; ICC, intraclass correlation coefficient; X, not reported.

TABLE 7 Levels of evidence for the quality of the questionnaires

Instrument		Internal consistency	Reliability	Measurement error	Content validity	Structural validity	Hypotheses testing for construct	Cross-cultural validity	Responsiveness
Condition-specific instrument	CCVUQ[28]	Very low	Very low		High	Very low	Low		Very low
	CCVUQ[27]								Low
	CCVUQ-Brazil[29]	High	Very low						
	CCVUQ-C[30]	High	Low			Moderate	Moderate		
	VLU-QoL[31]	High	Moderate		High	Very low	Moderate		Moderate
	VLU-QoL-Br[32]	Moderate	Low			Very low			
	Hyland questionnaire[33]	High				Moderate			
	SPVU-5D[34]	Low			Moderate				
	VEINES-QOL[26]	Very low	High			Moderate	Moderate		Moderate
Generic instrument	SF-36[27]								Low
	CGI[35]		Very low		Very low		Very low		
	EQ-5D[27,33]								Inconsistent
	SF-12[33]								Low
	NHP[36]	High					Low		Very low

Venous Ulcer Questionnaire (CCVUQ) was assessed in four studies in three different versions of languages.[27-30] Due to different language versions of this instrument and inconsistent results, four studies were assessed separately. The evidence of the results and ratings were reported separately. Two studies reported CCVUQ in English.[27,28] One study[27] reported responsiveness only and showed indeterminate responsiveness as there was no hypotheses reported for responsiveness. Another study that assessed English version of the CCVUQ[28] reported internal consistency, reliability, content validity, structural validity, hypotheses testing for construct and responsiveness. The CCVUQ showed very low level of evidence for indeterminate internal consistency (Cronbach's $\alpha = 0.93$). Very low level of evidence for reliability (test–retest analysis: $r = 0.84$) and indeterminate structural validity were found. The result of reliability did not fulfil the 'criteria for good measurement properties' and, thus, they were not rated. The CCVUQ showed high level of evidence for inconsistent content validity as they did not report the comprehensibility of the instruments.

The Chinese version of CCVUQ[30] showed a high level of evidence for sufficient internal consistency (Cronbach's $\alpha = 0.95$), low evidence for sufficient reliability (ICC $= 0.94$) and moderate evidence for sufficient structural validity (comparative fit index [CFI] $= 0.96$). There was moderate evidence for sufficient hypotheses testing for construct.

For the Brazilian Portuguese version of CCVUQ,[29] there was high level of evidence for indeterminate internal consistency (Cronbach's $\alpha = 0.92$). However, there were very low level of evidence for sufficient reliability (ICC: 0.897–0.963).

4.4.7 | Venous Leg Ulcer Quality of Life Questionnaire

Venous leg ulcer quality of life questionnaire (VLU-QoL) is a 34-item condition-specific QoL instrument with three dimensions: activities, psychological and symptoms.[31,32] The authors reported that VLU-QoL instruments were completed by participants themselves.[31] It took about 8–30 min to complete it.[32] There were two versions of the VLU-QoL instruments included in this review: English[31] and Brazilian Portuguese.[32] These two studies were assessed separately.

For the English version of VLU-QoL,[31] very low level of evidence for sufficient structural validity was found. There was high level of evidence for indeterminate internal consistency (Cronbach's a >0.8) and sufficient content validity. Moderate evidence for sufficient reliability (ICC $= 0.83$–0.86), sufficient hypotheses testing for construct and indeterminate responsiveness were found.

The Brazilian Portuguese version of VLU-QoL[32] showed very low evidence for sufficient structural validity. Both studies explored a three-factor solution. However, inadequate sample size in the factor analysis may cause bias and reduce the evidence of structural validity. There was moderate evidence for indeterminate internal consistency (Cronbach's $a = 0.94$). Low evidence for sufficient reliability (ICC $= 0.78$ and 0.9) was found.

4.4.8 | Hyland Questionnaire

Hyland questionnaire is a 34-item condition-specific QoL instrument with three main sections.[33] The first section is the condition of hospitalisation and a visual scale of ulcers condition.[33] The second section includes four items: leg ulcer pain, sleep discomfort, time thinking about the ulcer and time spent helping the ulcer healing.[33] The third section is a 29-item list concerning functional limitation, dystrophic mood and treatment associated with the presence of an open leg ulcer.[33] The instrument was used to assess QoL in individuals with open wound only, as reported in this study.[33] A factor analysis was conducted for the third section of the Hyland questionnaire, and a two-factor solution was confirmed. There was moderate evidence for insufficient structural validity. High quality of evidence for sufficient internal consistency (Cronbach's $a = 0.82$ and 0.79) was reported.

4.4.9 | Sheffield Preference-based Venous Ulcer questionnaire

SPVU-5D is a 16-item condition-specific QoL instrument consisting of four parameters: physical, psychological impact, social impact and ulcer impact.[34] The question type of this questionnaire is five point Likert scale.[34] Only one study[34] reported SPVU-5D. 64% of the participants were retired and many of the participants in this study suffered many symptoms, such as pain, exudate, depression, insomnia and adverse smell. There was low level of evidence for indeterminate internal consistency; and moderate evidence for inconsistent content validity was also found.

4.4.10 | Venous Insufficiency Epidemiological and Economic Study Quality of Life

VEINES-QOL is a 26-item condition-specific QoL instrument developed for chronic venous leg disorders.[26] This instrument was completed by participants.[26] A three-factor solution was explored in a factor analysis and moderate evidence for indeterminate structural validity was reported. There was high level of evidence for sufficient reliability. Moderate evidence for sufficient hypotheses testing for construct and unrated responsiveness was also found. The VEINES-QoL showed very low evidence for indeterminate internal consistency.

5 | DISCUSSION

We identified 13 QoL instruments reported in 11 studies that met the inclusion criteria. Recommendations on the most appropriate instruments for evaluating QoL in patients with VLUs were guided by the COSMIN guidelines[20] and included three identified categories.

- Category A includes instruments 'with evidence for sufficient content validity (any level) AND at least low-quality evidence for sufficient internal consistency'. Instruments belong to category A will be recommended for use and results can be trusted.[20]
- Category B includes instruments that are not in A or C. Instruments in Category B have potential to be recommended but require further research to evaluate the quality of these instruments.[20]
- Category C includes instrument with 'with high quality evidence for an insufficient measurement property'. Instruments categorised to category C should not be recommended for use.[20]

Based on the results of GRADE and ratings of measurement properties, all of the 14 QoL instruments were placed in category B, in which instrument has potential to be recommended but require further research on its measurement properties. Among all the QoL instruments in category B, the instrument with best evidence for content validity could be provisionally recommended for use until high quality evidence is found.[38] Considering current evidence of measurement properties for each QoL instrument, VLU-QoL could be provisionally used for assessing QoL in studies with VLUs patients until further evidence is provided or another accurate QoL instruments is designed.

The measurement properties of VLU-QoL showed high level evidence for a positive content validity and moderate evidence for a positive reliability and construct validity. High-level evidence supported the recommendation for the use of VLU-QoL in clinical practice. However, the study of VLU-QoL assessed the factor analysis of the structure in an inadequate sample size. The level of evidence for its structural validity and internal consistency was reduced. Therefore, further studies with large sample size are expected to confirm the structural validity and internal consistency of VLU-QoL. However, study included in this review did not report the time consuming of VLU-QoL.

There were few measurement properties reported for NHP, EQ-5D, SF-36, SF-12 and CGI. The evidence on reliability, content validity, construct validity and responsiveness of these generic instruments were almost low or very low. It is unlikely to recommend these generic QoL instruments in this review based on insufficient evidence.

Condition-specific QoL instruments, CCVUQ-Brazil, VLU-QoL-Br, Hyland questionnaire, CCVUQ-C, VEINES-QoL and FLQA lack adequate information of content validity. The studies of SPVU-5D and CCVUQ showed inconsistent content validity. These instruments cannot be recommended for use at this stage until further studies reported strong evidence for sufficient content validity of these QoL instruments. However, CCVUQ-C showed sufficient internal consistency, reliability, structural validity and hypotheses testing for construct. The study also showed a good content validity index (0.82) but without reporting relevance, comprehensiveness and comprehensibility of its content. This instrument may be used for Chinese-speaking patients with VLUs if there is no better QoL instruments available for Chinese-speaking patients with VLUs.

Responsiveness showed the ability of a QoL instruments to detect change over time. Many studies in this systematic review assessed responsiveness with different statistical methods. Some studies used ES or SRM to assess the responsiveness over time but there were no hypotheses for the expected magnitude of ES or SRM. Therefore, the results of responsiveness cannot be interpreted properly.

We were unable to find any studies that assessed measurement error and cross-cultural validity. Some studies in this systematic review reported criterion validity by comparing the target QoL instrument with widely used and well-known instruments such as SF-36. These studies[26,28,31,35] were considered to report construct validity based on the COSMIN guideline.[20]

This systematic review included studies that reported using five generic QoL instruments which assessed responsiveness. However, the inconsistent results could not provide evidence for responsiveness.

6 | LIMITATIONS

This systematic review adopted COSMIN guidelines to assess measurement properties comprehensively. However, we may have missed instrument validation studies available in grey literature and unpublished articles. Non-English studies were not included in this review and thus may result in limited searching results even though we believe that our search strategy and extracted studies were comprehensive to cover enough studies. As the COSMIN guideline was not available when many articles were first published, the studies of validating measurement properties of QoL instruments did not comply with the COSMIN guidelines. The measurement properties of those QoL instruments may be potentially underrated. In addition, studies involved in this review lack the information of time required for completion. This review was not able to provide the comparison of completion time for each instrument.

7 | RECOMMENDATIONS FOR FUTURE STUDIES

Future studies on the measurement properties of QoL instruments for patients with VLUs are needed to report accurate evidence on the measurement properties of QoL instruments used for VLUs patients.

When assessing the internal consistency, we suggest researchers firstly assess the structural validity with large sample size (at least five times the number of instruments items and over 100)[38] to reduce the chance of the standard error bias.[20] As for the reliability, an appropriate time interval between two administrations of QoL instruments should be discussed in the future studies, especially when interventions of VLUs were adopted in the study. In order to evaluate the criterion validity, review team should determine a gold standard of QoL instrument. None of the studies included in this review reported measurement error and cross-cultural validity. Future studies could include these two measurement properties and provide more evidence for future evaluations and recommendations. We suggest future studies evaluate content validity of CCVUQ-C before use and to confirm the structural validity of VLU-QoL in a larger sample size.

8 | CONCLUSION

This systematic review identified 13 QoL instruments reported in studies for people with VLUs. These included five generic QoL instruments and eight condition-specific QoL instruments. VLU-QoL was provisionally recommended for assessing the impact of VLUs on QoL for adults with active VLUs. With good content validity, reliability and construct validity, VLU-QoL can reflect the QoL of VLUs patients accurately. It could be used as an outcome for developing and distinguishing new treatment options or care plans in clinical practice and contributing to clinical decision making. However, when applying VLU-QoL to non-English speakers, a new validation studies of measurement properties of translated QoL instruments should be conducted prior to the research. This review did not report the time required for completion of VLU-QoL. Clinicians should be aware the time spent on VLU-QoL before they start their clinical research. Future research aimed to assess the structural validity and internal consistency of VLU-QoL need to ensure a sufficient sample size. To date, the structural validity and internal consistency of VLU-QoL have not been confirmed. Therefore, the needs of accurate QoL instruments and further studies on reliability, validity and responsiveness for VLUs instruments have been highlighted.

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APPENDIX

SEARCH STRATEGY—OVID MEDLINE

1	leg ulcer/or varicose ulcer/	12,910
2	Venous Insufficiency/	6627
3	((varicose or venous or leg or foot or feet or stasis or crural or lower extremit* or lower limb* or wound) adj2 ulcer*).ti,ab.	14,493
4	Ulc* cruris.mp.	683
5	1 or 2 or 3 or 4	25,706
6	"Quality of Life"/	216,423
7	"Activities of Daily Living"/	67,418
8	(quality of life or QoL or HRQoL or life qualit* or wellbeing or well-being or activities of daily living or daily living activit* or wellness or healthiness or health level or health status or happiness).mp.	578,882
9	6 or 7 or 8	578,882
10	(instrument* or survey* or questionnaire* or tool* or scale* or measure* or index or indices or rating* or indicator* or assessment or patient reported outcome*).mp.	6,808,231
11	"Surveys and Questionnaires"/	501,715
12	Patient Reported Outcome Measures/	8900
13	Health Surveys/	64,815
14	Patient health questionnaire/or self report/	37,664
15	10 or 11 or 12 or 13 or 14	6,812,675
16	Methods/	231,748
17	Psychometrics/	79,829
18	psychometr*.ti,ab.	42,861
19	(clinimetr* or clinometr*).mp.	1109
20	Outcome Assessment, Health Care/	76,749
21	Observer variation/	43,710
22	observer variation.ti,ab.	1020
23	Health Status Indicators/	23,857
24	"Reproducibility of Results"/	420,928
25	Discriminant Analysis/	11,288
26	(reproducib* or reliab* or unreliab* or valid* or coefficient of variation or coefficient or homogeneity or homogeneous or internal consistency).ti,ab.	1,350,449
27	(cronbach* and (alpha or alphas)).ti,ab.	20,798
28	(item and (correlation* or selection* or reduction*)).ti,ab.	20,660
29	(agreement or precision or imprecision or precise values).mp.	345,740
30	(test–retest or (test and retest)).ti,ab.	25,235
31	(reliab* and (test or retest)).ti,ab.	82,423
32	(stability or interrater or inter-rater or intrarater or intra-rater or intertester or inter-tester or intratester or intra-tester or interobserver or inter-observer or intraobserver or intra-observer or interexaminer or inter-examiner or intraexaminer or intra-examiner or interassay or inter-assay or intraassay or intra-assay or interindividual or inter-individual or intraindividual or intra-individual or kappa or kappa's or kappas).ti,ab.	498,145
33	repeatab*.mp.	30,506
34	((replicab* or repeated) and (measure or measures or findings or result* or test*)).mp.	201,143
35	(generaliza* or generalisa* or concordance).ti,ab.	80,531
36	(intraclass and correlation*).ti,ab.	23,777
37	(discriminative or known group or factor analysis or factor analyses or factor structure or factor structures or dimension* or subscale*).ti,ab.	521,359
38	(multitrait and scaling and analys#s).ti,ab.	132

(Continues)

39	(item discriminant or interscale correlation* or error or errors or individual variability or interval variability or rate variability).ti,ab.	275,943
40	(variability and (analysis or values)).ti,ab.	92,181
41	(uncertainty and (measurement or measuring)).ti,ab.	5406
42	(standard error of measurement or sensitiv* or responsive*).ti,ab.	1,457,086
43	((limit and detection) or minimal detectable concentration or interpretab*).ti,ab.	88,931
44	((minimal or minimally or clinical or clinically) and (important or significant or detectable) and (change or difference)).ti,ab.	220,318
45	(small* and (real or detectable) and (change or difference)).ti,ab.	6719
46	(meaningful change or ceiling effect or floor effect or Item response model or IRT or Rasch or Differential item functioning or DIF or computer adaptive testing or item bank or cross-cultural equivalence).ti,ab.	12,251
47	16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46	4,594,542
48	5 and 9 and 15 and 47	374
49	limit 48 to (English language and year = "2000–Current")	347