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The quality of health literacy instruments used in children and adolescents: which one is the best?

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The quality of health literacy instruments used in children and adolescents: which one is the best?

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ABSTRACT

Objective: Improving health literacy at an early age is crucial to childhood and adolescent health and development. Although health literacy in children and adolescents has gained increasing attention in the past decade, it remains an under-researched area, particularly health literacy measurement. Given that it is still unclear which health literacy instrument is the best in terms of its validity, reliability and feasibility for children and adolescents, this study aimed to examine the quality of health literacy instruments used in children and adolescents and to identify the best instrument for field use.

Design: Systematic review.

Setting: A wide range of settings including schools, hospitals and communities.

Participants: Children or adolescents aged 6 to 24.

Primary and secondary outcome measures: Measurement properties (i.e. reliability, validity and responsiveness) and other important characteristics (e.g. health topics, components and scoring systems) of health literacy instruments.

Results: There were 15 health literacy instruments identified from the screening process. When measuring health literacy in children and adolescents, researchers mainly focus on the functional domain and participant characteristics of cognitive development, dependency and demographic patterns. The methodological quality of included studies as assessed via measurement properties varied from poor to excellent. More than half (70.8%) of measurement properties were unknown, due to either poor methodological quality of included studies or a lack of reporting or assessment.

Conclusions: More rigorous and high-quality studies are needed to fill the knowledge gap in measurement properties of child and adolescent health literacy instruments. Although it is challenging to draw a robust conclusion about which instrument is the most reliable and the most valid, this review provides important evidence that

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3 supports the use of the 8-item Health Literacy Assessment Tool (HLAT-8) to measure
4 childhood and adolescent health literacy in future school-based research.
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7 **Keywords:** Measurement properties; health literacy; children; adolescents; systematic
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STRENGTHS AND LIMITATIONS OF THIS STUDY

- The COSMIN checklist was used as a methodological framework to rate the methodological quality of included studies.
- This review has updated previous reviews of childhood and adolescent health literacy measurement and identified eight additional health literacy instruments.
- Including only studies that aimed to develop or validate a health literacy instrument may eliminate studies that used a health literacy instrument for other purposes.
- Individual subjectivity exists in the screening and data synthesis stages.

INTRODUCTION

Health literacy is a personal resource that enables an individual to make decisions for healthcare, disease prevention and health promotion in everyday life.¹ As defined by the World Health Organisation,² health literacy refers to ‘*the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health.*’ The literature has shown that health literacy is an independent and more direct predictor of health outcomes than socio-demographics.^{3 4} People with low health literacy are likely to have worse health-compromising behaviours, higher healthcare costs and poorer health status.⁵ Given the close relationship between health literacy and health outcomes, many countries have adopted the promotion of health literacy as a key strategy to reduce health inequities.⁶

From a health promotion perspective, improving health literacy at an early age is crucial to childhood and adolescent health and development.⁷ As demonstrated by Diamond *et al.*⁸ and Robinson *et al.*,⁹ health literacy interventions for children and adolescents can bring about improvements in healthy behaviours and decreased use of emergency department services. Although health literacy in young people has gained increasing attention, with a rapidly growing number of publications in the past decade,¹⁰⁻¹² childhood and adolescent health literacy is still under-researched. According to Forrest *et al.*'s 4D model,^{13 14} health literacy in children is mediated by four additional factors compared to adults: (1) *developmental* change: children have less well-developed cognitive ability than adults; (2) *dependency*: children depend more on their parents and peers than adults do; (3) *differential* epidemiology: children experience a unique pattern of health, illness and disability; and (4) *demographic* patterns: many children and adolescents living in poverty or in single-parent families are neglected and so require additional care. These four differences pose significant challenges for researchers when measuring health literacy in children and adolescents.

Health literacy is a broad and multi-dimensional concept with varying definitions.¹⁵ This paper uses the definition by Nutbeam who states that health literacy consists of three domains: functional, interactive and critical¹⁶. The *functional* domain refers to basic skills in reading and writing health information, which are important for

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3 functioning effectively in everyday life. The *interactive* domain represents advanced
4 skills that allow individuals to extract health information and derive meaning from
5 different forms of communication. And the *critical* domain represents more advanced
6 skills that can be used to critically evaluate health information and take control over
7 health determinants.¹⁶ Although health literacy is sufficiently explained in terms of its
8 definitions¹⁶⁻¹⁸ and theoretical models,^{4,7} its measurement remains a contested issue.
9 There are two possible reasons for this. One reason is the large variety of health
10 literacy definitions and conceptual models,^{12,15} and the other reason is that researchers
11 may have different study aims, populations and contexts when measuring health
12 literacy.^{19,20}

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21 Currently, there are two systematic reviews describing and analysing the methodology
22 and measurement of childhood and adolescent health literacy.^{10,11} In 2013, Ormshaw
23 *et al.*¹⁰ conducted a systematic review of child and adolescent health literacy
24 measures. This review used four questions to explore health literacy measurement in
25 children and adolescents: “*What measurement tools were used? What health topics*
26 *were involved? What components were identified? and Did studies achieve their*
27 *stated aims?*” The authors identified 16 empirical studies, with only six of them
28 evaluating health literacy measurement as their primary aim. The remaining studies
29 used health literacy measures as either a comparison tool when developing other new
30 instruments or as a dependent variable to examine the effect of an intervention
31 program. Subsequently, in 2014, Perry¹¹ conducted an integrative review of health
32 literacy instruments used in adolescents. In accordance with the eligibility criteria,
33 five instruments were identified.

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43 Although these two reviews provide general knowledge about the methodology and
44 measurement of health literacy in young people, both have limitations. Ormshaw *et*
45 *al.*¹⁰ did not evaluate measurement properties of each health literacy instrument.
46 Although Perry¹¹ summarised measurement properties of each instrument, the
47 information provided was limited and mostly descriptive, and lacked a critical
48 appraisal. Notably, Ormshaw *et al.*¹⁰ and Perry¹¹ did not consider the methodological
49 quality of the included studies. A lack of quality assessment of studies raises concerns
50 about the utility of such reviews for evaluating and selecting health literacy
51 instruments for children and adolescents. Therefore, it is still unclear which
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instrument is the best in terms of its validity, reliability and feasibility for field use. In addition, it is also unclear how Nutbeam's three-domain health literacy model and Forrest *et al.*'s 4D model are considered in existing health literacy instruments for children and adolescents.

To fill these knowledge gaps, this study aimed to conduct a systematic review to examine the quality of health literacy instruments used in the young population and to identify the best instrument for field use. We expected the findings would assist researchers in identifying and selecting the most appropriate instrument for different purposes when measuring childhood and adolescent health literacy.

METHODS

Following the methods for conducting systematic reviews outlined in the Cochrane Handbook,²¹ we developed a review protocol (See **Appendix 1**) prior to commencing the study. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement²² (See **Research Checklist**) was used to ensure the reporting quality of this review.

Literature search

The term '*health literacy*' was first used in 1974,²³ and so seven electronic databases were used to search for articles published between 1 January 1974 and 30 May 2014: Medline, PubMed, Embase, PsycINFO, CINAHL, ERIC and the Cochrane Library. The search strategy was designed on the basis of previous reviews^{5 10 24 25} and in consultation with two librarian experts. Three types of search terms were used: (1) construct-related terms: '*health literacy*' OR '*health and education and literacy*'; (2) outcome-related terms: '*health literacy assess**' OR '*health literacy measure**' OR '*health literacy evaluat**' OR '*health literacy instrument**' OR '*health literacy tool**'; and (3) age-related terms: '*child**' OR '*adolescent**' OR '*student**' OR '*youth*' OR '*young people*' OR '*teen**' OR '*young adult*'.

No language restriction was applied. The detailed search strategy for each database is available in **Appendix 2**. As per the PRISMA flow diagram,²² the references from

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3 included studies and from six previously published systematic reviews on health
4 literacy^{5 10 24-27} were also included.
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7 8 **Eligibility criteria**

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10 Studies had to fulfil the following criteria to be included: (1) the stated aim of the
11 study was to develop or validate a health literacy instrument; (2) participants were
12 children or adolescents aged 6 to 24; (3) the term ‘*health literacy*’ was explicitly
13 defined, although studies assessing health numeracy (the ability to understand and use
14 numbers in healthcare settings) were also considered; and (4) at least one
15 measurement property (reliability, validity and responsiveness) was reported in the
16 outcomes.
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19 Studies were excluded if: (1) the full paper was not available (e.g. conference
20 abstracts); (2) they were not peer-reviewed (e.g. dissertations, government reports); or
21 (3) they were qualitative studies.
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24 25 **Selection process**

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27 All references were imported into EndNote X7 software (Thomson Reuters, New
28 York, NY). Duplicate records were initially removed before screening. One author
29 (GS) screened all studies based on title and abstract. Full-text papers of the remaining
30 titles and abstracts were then obtained and screened by two independent authors (GS
31 and SA). At each major step of this systematic review, discrepancies between authors
32 were resolved through discussion.
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35 36 **Data extraction**

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38 Data were extracted from full-text papers by two independent authors (GS and TS).
39 The extracted data included: characteristics of included studies (e.g. first author,
40 published year and country), general characteristics of included instruments used in
41 the included studies (e.g. health topics, components and scoring systems),
42 methodological quality of included studies (e.g. internal consistency, reliability and
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measurement error) and ratings of measurement properties of included instruments (e.g. internal consistency, reliability and measurement error).

Methodological quality assessment of included studies

The methodological quality of included studies was assessed using the COSMIN checklist.²⁸ The COSMIN checklist is a critical appraisal tool containing standards for evaluating the methodological quality of studies on measurement properties of health measurement instruments.²⁹ Specifically, nine measurement properties (internal consistency, reliability, measurement error, content validity, structural validity, hypotheses testing, cross-cultural validity, criterion validity and responsiveness) were assessed.²⁹ Since there is no agreed-upon ‘*gold standard*’ for health literacy measurement,^{30 31} criterion validity was not assessed in this review. Each measurement property section contains 5 to 18 evaluating items. For example, ‘*internal consistency*’ is evaluated against 11 items. Each item is scored using a four-point scoring system (‘*excellent*’, ‘*good*’, ‘*fair*’ or ‘*poor*’). The overall methodological quality of a study is obtained for each measurement property separately, by taking the lowest rating of any item in that section (i.e. ‘*worst score counts*’). Two authors (GS and TS) independently assessed the methodological quality of included studies.

Evaluation of measurement properties for included instruments

The quality of each measurement property of an instrument was evaluated using quality criteria proposed by Terwee *et al.*³², who are members of the group that developed the COSMIN checklist (See **Appendix 3**). Each measurement property was given a rating result (‘+’ positive, ‘-’ negative, ‘?’ indeterminate and ‘*na*’ no information available).

Best evidence synthesis: levels of evidence

As recommended by the COSMIN checklist developer group,²⁹ ‘*a best evidence synthesis*’ was used to synthesise all the evidence on measurement properties of different instruments. The procedure used was similar to the Grading of

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3 Recommendations, Assessment, Development and Evaluation (GRADE) framework³³,
4 a transparent approach to rating quality of evidence that is often used in reviews of
5 clinical trials.³⁴ Given that this review did not target clinical trials, the GRADE
6 framework adapted by the COSMIN group was used.³⁵ Under this procedure, the
7 possible overall rating for a measurement property is ‘*positive*’, ‘*negative*’,
8 ‘*conflicting*’ or ‘*unknown*’, accompanied by levels of evidence (‘*strong*’, ‘*moderate*’
9 or ‘*limited*’) (See **Appendix 4**). Specifically, three steps were taken to obtain the
10 overall rating for a measurement property. First, the methodological quality of a study
11 on each measurement property was assessed using the COSMIN checklist.²⁸
12 Measurement properties from ‘*poor*’ methodological quality studies did not contribute
13 to ‘*the best evidence synthesis*’. Second, the quality of each measurement property of
14 an instrument was evaluated using Terwee’s quality criteria.³² Third, the rating results
15 of measurement properties in different studies on the same instrument were examined
16 whether consistent or not. This best evidence synthesis was performed by one author
17 (GS) and then checked by a second author (TS).
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29 **Results**

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32 The search identified 1804 studies. After duplicates and initial title/abstract screening,
33 303 full-text articles were identified and obtained. As per the eligibility criteria, 15
34 studies were included,³⁶⁻⁵⁰ yielding 15 unique health literacy instruments used in
35 children and adolescents (See **Figure 1**).
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40 **Characteristics of included studies**

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43 Among the 15 studies identified, 11 were published in the last five years (2010 to
44 2014) (See **Table 1**). Most included studies were conducted in Western countries
45 (n=13), with seven studies carried out in the USA. The target population aged 7 to 25
46 could be roughly classified into three subgroups: children aged 7 to 12 (n=3),
47 adolescents aged 13 to 17 (n=10) and young adults aged 18 to 25 (n=2). Schools (n=9)
48 were the most common recruitment settings, compared to clinical settings (n=4) and
49 communities (n=2).
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Table 1. Characteristics of included studies

Study no	Author (Year)	Country	Target population	Health literacy instrument	Sample size (% male)	Sampling method	Recruitment setting
1	Davis <i>et al.</i> ³⁸ (2006)	USA	Adolescents aged 10-19 years (mean age=14.8±1.9)	REALM-Teen	1533 (47.4)	na	Middle schools, high schools, paediatric primary care clinic and summer programs
2	Norman and Skinner ⁴⁰ (2006)	Canada	Adolescents aged 13-21 years (mean age=14.95±1.24)	eHEALS	664 (55.7)	Sampling from one arm of a randomised controlled trial	Secondary schools
3	Chisolm and Buchanan ⁴⁵ (2007)	USA	Young people aged 13-17 years (mean age=14.7)	TOFHLA	50 (48.0)	na	Children's hospital
4	Steckelberg <i>et al.</i> ⁴⁴ (2009)	Germany	Students in Grade 10-11 and university	CHC Test	Sample 1: 322 (36.6) Sample 2: 107 (32.7)	na	Secondary schools, university
5	Schmidt <i>et al.</i> ⁴³ (2010)	Germany	Children aged 9-13 years (mean age=10.4)	HKACSS	852 (52.9)	na	Primary school
6	Wu <i>et al.</i> ³⁷ (2010)	Canada	Students in Grade 8-12	HLAB	275 (48.0)	Convenience sampling	Secondary schools
7	Levin-Zamir <i>et al.</i> ⁴⁶ (2011)	Israel	Adolescents in Grade 7, 9, 11 (approximately age 13, 15 and 17)	MHL	1316 (52.0)	Probability sampling and random cluster sampling	Public schools
8	Chang <i>et al.</i> ⁴⁸ (2012)	Taiwan	Students in high school (mean age=16.01±1.02)	c-sTOFHLAd	300 (52.6)	Multiple-stage stratified random sampling	High schools
9	Hoffman <i>et al.</i> ⁴⁷ (2013)	USA	Youth aged 14-19 years (mean age=17)	REALM-Teen; NVS; s-TOFHLA	229 (61.6)	na	Private high school
10	Massey <i>et al.</i> ⁴¹ (2013)	USA	Adolescents aged 13-17 years (mean age=14.8)	MMAHL	1208 (37.6)	Sampling from a large health insurance network	Publicly health insurance network
11	Mulvaney <i>et al.</i> ⁵⁰ (2013)	USA	Adolescents aged 12-17 years (Sample 1: mean age=13.92; Sample 2: mean age=15.10)	DNT-39 and DNT-14	Sample 1: 61 (52.5) Sample 2: 72 (55.6)	na	Diabetes clinics
12	Abel <i>et al.</i> ⁴²	Switzerland	Young adults aged 18-25 years	HLAT-8	7428 (95.5)	Sampling from compulsory	Compulsory military

Study no	Author (Year)	Country	Target population	Health literacy instrument	Sample size (% male)	Sampling method	Recruitment setting
	(2014)		(male mean age: 19.6; female mean age=18.8)			military service for males and two-stage random sampling for females	service, communities
13	Driessnack <i>et al.</i> (2014)	USA	Children aged 7-12 years	NVS	47 (53.0)	Convenience sampling	The science centre
14	Harper ³⁹ (2014)	New Zealand	Students aged 18-24 years	HLAT-51	144 (41.0)	Purposeful sampling	College
15	Warsh <i>et al.</i> ³⁶ (2014)	USA	Children aged 7-17 years (median age=11)	NVS	97 (46.0)	Convenience sampling	Paediatric clinics

Note: na, no information available. CHC Test, the Critical Health Competence Test; c-sTOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TOFHLA, the Test of Functional Health Literacy in Adults.

General characteristics of included instruments

Compared to previous systematic reviews,^{10 11} this review identified eight additional health literacy instruments (NVS, s-TOFHLA, MMAHL, DNT-39, DNT-14, eHEALS, HLAT-51 and HLAT-8). The 15 health literacy instruments were classified into three groups based on whether the instrument was developed bespoke for the study or not (See **Table 2**).¹⁰ The three groups were: (1) newly-developed instruments for childhood and adolescent health literacy (n=9);^{37-44 46 47} (2) adapted instruments that were based on previous instruments for adult health literacy (n=3);^{48 50} and (3) original instruments that were developed for adult health literacy (n=3).^{36 45 47 49}

Health literacy domains and components

Next, Nutbeam's three-domain health literacy model¹⁶ was used to classify the 15 instruments according to which of the commonly-used components of health literacy were included. Results showed that seven instruments measured only functional health literacy^{36 38 45 47-50} and one instrument measured only critical health literacy.⁴⁴ There was one instrument measuring functional and interactive health literacy⁴³ and one measuring functional and critical health literacy.³⁷ Five instruments measured health literacy by all three domains (functional, interactive and critical).^{39-42 46}

Consideration of participants' characteristics

As per Forrest *et al.*'s 4D model,^{13 14} the 15 included instruments were examined for whether participant characteristics were considered when developing a new instrument or validating an existing instrument. Results showed most of the health literacy instruments considered developmental change, dependency and demographic patterns. In contrast, only two instruments considered differential epidemiology.⁵⁰

Health topics, contents and readability levels

Health literacy instruments for children and adolescents covered a range of health topics such as nutrition and sexual health. Most instruments (n=12) measured health literacy in healthcare settings or health promotion contexts, while only three

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3 instruments measured health literacy in the specific context of eHealth or media
4 health.^{39 40 46} In relation to the readability of tested materials, only five health literacy
5 instruments reported their readability levels, ranging from 4th to 19.5th grade.
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8 9 Burden and forms of administration

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12 The time to administer was reported in seven instruments, and ranged from 3 to 90
13 minutes. There were three forms of administration: interviewer-administered
14 instruments (n=7), self-administered instruments (n=7) and video-assisted,
15 interviewer-administered instruments (n=1). As for the method of assessment, ten
16 instruments were performance-based, three instruments were self-report, and two
17 included both performance-based and self-report items.
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Table 2. General and important characteristics of included instruments used in children and adolescents

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
1	NVS ^{36,47,49}	Functional HL 1. Reading comprehension (2) 2. Numeracy (4)	Demographic patterns	Nutrition-related information about the label of an ice cream container (na)	Open-ended	Score: 0-6; Ordinal category: 0-1: high likelihood of limited literacy; 2-3: possibility of limited literacy; 4-6: adequate literacy	No longer than 3 minutes	Interviewer-administered & Performance-based
2	TOFHLA ⁴⁵	Functional HL 1. Reading comprehension (50) 2. Numeracy (17)	Developmental change Demographic patterns	Instruction for preparation for an upper gastrointestinal series (4.3 grade), a standard informed consent form (10.4 grade), patients' rights and responsibilities section of a Medicaid application form (19.5 grade), actual hospital forms & labelled prescription vials (9.4 grade)	4 response options	Score: 0-100; Ordinal category: 0-59: inadequate health literacy; 60-74: marginal health literacy; 75-100: adequate health literacy	12.9 minutes (8.9-17.3 minutes)	Interviewer-administered & Performance-based
3	s-TOFHLA ⁴⁷	Functional HL 1. Reading comprehension (36)	Demographic patterns	Instruction for preparation for an upper gastrointestinal series (4 th grade), patients' rights and responsibilities section of a Medicaid application form (10 th grade)	4 response options	Score: 0-36; Ordinal category: 0-16: inadequate literacy; 17-22: marginal literacy; 23-36: adequate literacy	na	Interviewer-administered & Performance-based
4	c-sTOFHLa ⁴⁸	Functional HL 1. Reading comprehension (36)	Developmental change Demographic patterns	Instruction for preparation for an upper gastrointestinal series (4 th grade), patients' rights and responsibilities section of a Medicaid application form (10 th grade)	4 response options	Score: 0-36; Ordinal category: 0-16: inadequate literacy; 17-22: marginal literacy; 23-36: adequate literacy	20-minute class period	Self-administered & Performance-based
5	REALM-Teen ^{38,47}	Functional HL 1. Reading recognition (66)	Developmental change Demographic patterns	66 health-related words such as weight, prescription and tetanus (6 th grade)	Open-ended	Score: 0-66; Ordinal category: 0-37: ≤ 3 rd ; 38-47: 4 th -5 th ; 48-58:	2-3 minutes	Interviewer-administered & Performance-

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
6	HLAB ³⁷	Functional and critical HL 1. Understanding health information (30) 2. Evaluating health information (17)	Developmental change Demographic patterns	A range of topics such as nutrition and sexual health (pilot-tested)	Open-ended	6 th -7 th ; 59-62: 8 th -9 th ; 63-66: ≥ 10 th Score: 0-107; Continuous category	Two regular classroom sessions	based Self-Administered & Performance-based
7	MMAHL ⁴¹	Functional, interactive and critical HL 1. Patient-provider encounter (4) 2. Interaction with the health care system (5) 3. Rights and responsibilities (7) 4. Confidence in using health information from personal source (3) 5. Confidence in using health information from media source (3) 6. Health information seeking competency using the Internet (2)	Developmental change Demographic patterns Dependency	Experiences of how to access, navigate and manage one's health care and preventive health needs (6 th grade)	5-point Likert scale	Score: na; Continuous category	na	Self-administered & Self-reported
8	MHL ⁴⁶	Functional, interactive and critical HL 1. Content identification (6) 2. Perceived influence on behaviour (6) 3. Critical analysis and intended (6) 4. Action/reaction (6)	Dependency Demographic patterns	Nutrition/dieting, physical activity, body image, sexual activity, cigarette smoking, alcohol consumption, violent behaviour, safety habits and/or friendship and family connectedness (pilot-tested)	Open-ended & multiple choice	Score: 0-24; Continuous category	na	Video-assisted interviewer-administered & Performance-based

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
9	DNT-39 ⁵⁰	Functional health literacy 1. Health numeracy (39)	Differential epidemiology Demographic patterns	Nutrition, exercise, blood glucose monitoring and insulin administration (na)	Open-ended	Score: 0-100; Continuous category	na	Interviewer-administered & Performance-based
10	DNT-14 ⁵⁰	Functional health literacy 1. Health numeracy (14)	Differential epidemiology Demographic patterns	Nutrition, exercise, blood glucose monitoring and insulin administration (na)	Open-ended	Score: 0-100; Continuous category	na	Interviewer-administered & Performance-based
11	eHEALS ⁴⁰	Functional, interactive and critical HL 1. Accessing health information (4) 2. Evaluating health information (2) 3. Applying health information (2)	Developmental change Dependency Demographic patterns	General health topics about online health information (pilot-tested)	5-point Likert scale	Score: na; Continuous category	na	Self-Administered & Self-reported
12	CHC Test ⁴⁴	Critical HL 1. Understanding medical concepts (15) 2. Searching literature skills (22) 3. Basic statistics (18) 4. Design of experiments and sampling (17)	Developmental change Demographic patterns	Echinacea and common cold, magnetic resonance imaging in knee injuries, treatment of acne, breast cancer screening (pilot-tested)	Open-ended & multiple choice	na	Less than 90 minutes	Interviewer-administered & Performance-based
13	HKACSS ⁴³	Functional and interactive HL 1. Health knowledge (3) 2. Health attitudes (4) 3. Health communication (3) 4. Self-efficacy (3)	Developmental change Dependency Demographic patterns	Physical activities, nutrition, smoking, vaccination, tooth health and general health (na)	2 response options; 5-point Likert scale; 4-point Likert scale	Score: na; Continuous category	na	Self-Administered & Performance-based & Self-reported

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
14	HLAT-51 ³⁹	Functional, interactive and critical HL 1. Comprehension skill (20) 2. Health numeracy (11) 3. Media literacy (8) 4. Digital literacy (12)	Developmental change Dependency Demographic patterns	Health topics such as gout and uric acid, high cholesterol and triglyceride levels, health-information-seeking skills (na)	Yes/no; multiple choice	na	30-45 minutes	Self-administered & Performance-based & Self-reported
15	HLAT-8 ⁴²	Functional, interactive and critical HL 1. Understanding health information (2) 2. Finding health information (2) 3. Interactive health literacy (2) 4. Critical health literacy (2)	Dependency Demographic patterns	General health topics in people's daily life (na)	5-point Likert scale; 4-point Likert scale	Score: 0-37; Continuous category	na	Self-administered & Self-reported

Note: na, no information available. CHC Test, the Critical Health Competence Test; c-sTOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HL, Health Literacy; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; IOM, the Institute of Medicine; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TOFHLA, the Test of Functional Health Literacy in Adults; WHO, the World Health Organization.

Evaluation of methodological quality of included studies

According to the COSMIN checklist,²⁸ the methodological quality of each instrument as assessed by each study is presented in **Table 3**. All studies (n=15) examined content validity, 12 studies assessed internal consistency and hypotheses testing, six studies examined structural validity, five studies assessed reliability, and only one study assessed cross-cultural validity.

Evaluation of instruments' measurement properties

After the methodological quality assessment of included studies, measurement properties of each health literacy instrument were examined according to Terwee's quality criteria (See **Appendix 5**).³² The rating results of measurement properties of each instrument are summarised in **Table 4**.

The synthesised evidence for the overall rating of measurement properties

Finally, a synthesis was conducted for the overall rating of measurement properties for each instrument according to '*the best evidence synthesis*' guidelines recommended by the COSMIN checklist developer group.²⁹ This synthesis result was derived from information presented in **Table 3** and **Table 4**. The overall rating of each measurement property for each health literacy instrument is presented in **Table 5**. In summary, most information (70.8%, 85/120) on measurement properties was unknown due to either poor methodological quality of studies or a lack of information on reporting or assessment.

Table 3. Methodological quality of each study for each measurement property according to the COSMIN checklist

Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsiveness
					Structural validity	Hypotheses testing	Cross-cultural validity	
NVS (Hoffman <i>et al.</i> , 2013) ⁴⁷	Poor	na	na	Poor	na	Fair	na	na
NVS (Driessnack <i>et al.</i> , 2014)	Poor	na	na	Poor	na	Poor	na	na
NVS (Warsh <i>et al.</i> , 2014) ³⁶	na	na	na	Poor	na	Fair	na	na
TOFHLA (Chisolm and Buchanan, 2007) ⁴⁵	na	na	na	Poor	na	Fair	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013) ⁴⁷	Poor	na	na	Poor	na	Fair	na	na
c-sTOFHLAd (Chang <i>et al.</i> , 2012) ⁴⁸	Fair	Fair	na	Good	Fair	Fair	Fair	na
REALM-Teen (Davis <i>et al.</i> , 2006) ³⁸	Poor	Fair	na	Good	na	Fair	na	na
REALM-Teen (Hoffman <i>et al.</i> , 2013) ⁴⁷	Poor	na	na	Poor	na	Poor	na	na
HLAB (Wu <i>et al.</i> , 2010) ³⁷	Fair	Poor	na	Good	na	Fair	na	na
MMAHL (Massey <i>et al.</i> , 2013) ⁴¹	Good	na	na	Good	Good	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011) ⁴⁶	Poor	na	na	Good	na	Good	na	na
DNT-39 (Mulvaney <i>et al.</i> , 2013) ⁵⁰	Fair	na	na	Poor	na	Fair	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013) ⁵⁰	Fair	na	na	Poor	na	Fair	na	na
eHEALS (Norman and Skinner, 2006) ⁴⁰	Fair	Fair	na	Good	Fair	Fair	na	na
CHC Test (Steckelberg <i>et al.</i> , 2009) ⁴⁴	na	Poor	na	Good	Poor	na	na	na
HKACSS (Schmidt <i>et al.</i> , 2010) ⁴³	Excellent	na	na	Good	na	Good	na	na
HLAT-51 (Harper, 2014) ³⁹	Poor	na	na	Good	Poor	na	na	na
HLAT-8 (Abel <i>et al.</i> , 2014)	Excellent	na	na	Poor	Excellent	Good	na	na

Note: na, no information available. CHC Test, the Critical Health Competence Test; c-sTOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TOFHLA, the Test of Functional Health Literacy in Adults.

Table 4. Evaluation of measurement properties for included instruments according to Terwee's quality criteria

Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsiveness
					Structural validity	Hypotheses testing	Cross-cultural validity	
NVS (Hoffman <i>et al.</i> , 2013) ⁴⁷	-	na	na	?	na	-	na	na
NVS (Driessnack <i>et al.</i> , 2014) ⁴⁹	+	na	na	?	na	-	na	na
NVS (Warsh <i>et al.</i> , 2014) ³⁶	na	na	na	?	na	+	na	na
TOFHLA (Chisolm and Buchanan, 2007) ⁴⁵	na	na	na	?	na	+(TOFHLA-R) -(TOFHLA-N)	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013) ⁴⁷	+	na	na	?	na	-	na	na
c-sTOFHLaD (Chang <i>et al.</i> , 2012)	+	+	na	+	?	+	?	na
REALM-Teen (Davis <i>et al.</i> , 2006) ³⁸	+	+	na	+	na	+	na	na
REALM-Teen (Hoffman <i>et al.</i> , 2013) ⁴⁷	+	na	na	?	na	-	na	na
HLAB (Wu <i>et al.</i> , 2010) ³⁷	+	+	na	+	na	-	na	na
MMAHL (Massey <i>et al.</i> , 2013) ⁴¹	+	na	na	+	-	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011) ⁴⁶	+	na	na	+	na	+	na	na
DNT-39 (Mulvaney <i>et al.</i> , 2013) ⁵⁰	+	na	na	?	na	-	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013) ⁵⁰	+	na	na	?	na	-	na	na
eHEALS (Norman and Skinner, 2006) ⁴⁰	+	-	na	+	+	-	na	na
CHC Test (Steckelberg <i>et al.</i> , 2009) ⁴⁴	na	+	na	+	+	na	na	na
HKACSS (Schmidt <i>et al.</i> , 2010) ⁴³	+(Health communication) -(Health attitude)	na	na	+	na	+	na	na
HLAT-51 (Harper, 2014)	?	na	na	+	?	na	na	na
HLAT-8 (Abel <i>et al.</i> , 2014) ⁴²	-	na	na	?	+	+	na	na

Note: na, no information available; + positive rating; ? indeterminate rating; - negative rating. CHC Test, the Critical Health Competence Test; c-sTOFHLaD, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TOFHLA, the Test of Functional Health Literacy in Adults; TOFHLA-N, the Numeracy part of the Test of Functional Health Literacy in Adults; TOFHLA-R, the Reading part of the Test of Functional Health Literacy in Adults.

Table 5. The overall quality of measurement properties for each health literacy instrument used in children and adolescents

Health instrument	literacy	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsive-ness
						Structural validity	Hypotheses testing	Cross-cultural validity	
NVS ^{36,47,49}		?	na	na	?	na	±	na	na
TOFHLA ⁴⁵		na	na	na	?	na	+ (TOFHLA-R) - (TOFHLA-N)	na	na
s-TOFHLA ⁴⁷		?	na	na	?	na	-	na	na
c-sTOFHLAd ⁴⁸		+	+	na	++	?	+	?	na
REALM-Teen ^{38,47}		?	+	na	++	na	+	na	na
HLAB ³⁷		+	?	na	++	na	-	na	na
MMAHL ⁴¹		++	na	na	++	--	na	na	na
MHL ⁴⁶		?	na	na	++	na	++	na	na
DNT-39 ⁵⁰		+	na	na	?	na	-	na	na
DNT-14 ⁵⁰		+	na	na	?	na	-	na	na
eHEALS ⁴⁰		+	-	na	++	+	-	na	na
CHC Test ⁴⁴		na	?	na	++	?	na	na	na
HKACSS ⁴³		+++ (Health communication) --- (Health attitude)	na	na	++	na	++	na	na
HLAT-51 ³⁹		?	na	na	++	?	na	na	na
HLAT-8 ⁴²		---	na	na	?	+++	++	na	na

Note: na, no information available; +++ or --- strong evidence and positive/negative result; ++ or -- moderate evidence and positive/negative result; + or - limited evidence and positive/negative result; ± conflicting evidence; ? unknown, due to poor methodological quality or indeterminate rating of a measurement property. CHC Test, the Critical Health Competence Test; c-sTOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TOFHLA, the Test of Functional Health Literacy in Adults; TOFHLA-N, the Numeracy part of the Test of Functional Health Literacy in Adults; TOFHLA-R, the Reading part of the Test of Functional Health Literacy in Adults.

Discussion

Summary of main results

This study identified and examined 15 health literacy instruments used in children and adolescents and exemplified the large variety of methods to measure childhood and adolescent health literacy. It shows that to date, health literacy instruments generally focus on the functional domain, and less on the interactive and critical domains. When measuring health literacy in children and adolescents, researchers mainly focus on participant characteristics of developmental change, dependency and demographic patterns, rather than differential epidemiology. The methodological quality of included studies as assessed via measurement properties varied from poor to excellent. Most information (70.8%) on measurement properties was unknown due to either the poor methodological quality of studies or a lack of reporting or assessment. It is therefore difficult to draw a robust conclusion about which instrument is the best.

Health literacy measurement in children and adolescents

This review found that health literacy measurement in children and adolescents still focused on the functional domain (n=7) rather than three domains (n=5). Unlike health literacy research for patients in clinics, health literacy research for children and adolescents (a comparatively healthy population) should be considered from a health promotion perspective,⁵¹ rather than a health care or disease management perspective. Integrating interactive and critical domains into health literacy measurement is aligned with the rationale of emphasising empowerment in health promotion for children and adolescents.⁵² The focus of health literacy for this population group should therefore include all three domains and so there is a need for future research to integrate the three domains within health literacy instruments.

Similar to previous findings by Ormshaw *et al.*,¹⁰ this review also revealed that childhood and adolescent health literacy measurement varied by its dimensions, health topics, forms of administration, and by the level to which participant characteristics were considered. There

are likely four main reasons for these disparities. First, definitions of health literacy were inconsistent. Some researchers measured general health literacy,^{37 42} while others measured eHealth literacy or media health literacy.^{40 46} Second, researchers had different research purposes for their studies. Some researchers used what were originally adult instruments to measure adolescent health literacy,^{36 45 49} whereas others developed new or adapted instruments.^{37-39 50} Third, the research settings affected the measurement process. As clinical settings were busy, short surveys were more appropriate than long surveys.^{36 38 41} On the other hand, health literacy in school settings was often measured by long and comprehensive surveys.^{37 39 44} Fourth, researchers considered different participant characteristics when measuring health literacy in children and adolescents. For example, some researchers took considerations of students' cognitive development,^{37 38 41 43 48} some focused on adolescents' resources and environments (e.g. friends and family contexts, eHealth contexts, media contexts),^{40 42 46} and others looked at the effect of different cultural backgrounds and socio-economic status.^{37 38 40 41 43 44 46-49} Based on Forrest *et al.*'s 4D model,^{13 14} this review showed that most health literacy instruments considered participants' development, dependency and demographic patterns, with only two instruments considering differential epidemiology.⁵⁰ Although the '4D' model cannot be used to reduce the disparities in health literacy measurement, it does provide an opportunity to identify gaps in current research and assist researchers to consider participants' characteristics comprehensively in future research.

The methodological quality of included studies

This review included a methodological quality assessment of included studies, which was absent from previous reviews on this subject.^{10 11} Methodological quality assessment is important because strong conclusions about the measurement properties of instruments can only be drawn from high-quality studies. In this review, the COSMIN checklist was shown to be a useful framework for critically appraising the methodological quality of studies via each measurement property. Findings suggested that there was wide variation in the methodological quality of studies for all instruments. Poor methodological quality of studies was often seen in the original or adapted health literacy instruments (the NVS, the TOFHLA, the s-TOFHLA, the DNT-39 and the DNT-14) for two main reasons. The first reason was the vague description of the target population involved. This suggested that researchers were less

likely to consider an instrument's content validity when using the original, adult instrument for children and adolescents. Given that children and adolescents have less well-developed cognitive abilities, it is essential to assess whether all items within an instrument are understood in future. The second reason was a lack of uni-dimensionality analysis for internal consistency. As explained in the COSMIN manual,⁵³ a set of items can be inter-related and multi-dimensional, uni-dimensionality is a prerequisite for a clear interpretation of the internal consistency statistics (Cronbach's alpha). Future research on the use of health literacy instruments therefore needs to assess and report both internal consistency statistics and uni-dimensionality analysis (e.g. factor analysis).

Critical appraisal of measurement properties for included instruments

This review demonstrated that of all instruments reviewed only the c-sTOFHLAd showed satisfactory internal consistency and test-retest reliability. The c-sTOFHLAd was a translated tool of the s-TOFHLA from English to Chinese.⁴⁸ Compared to the overall reliability rating of the s-TOFHLA,⁴⁷ the c-sTOFHLAd showed better results. The reason for this was probably the different methodological quality of included studies between the s-TOFHLA and the c-sTOFHLAd. The c-sTOFHLAd study had fair methodological quality in terms of internal consistency and test-retest reliability, whereas the original s-TOFHLA study had poor methodological quality for internal consistency and unknown information for test-retest reliability. Given the large disparity of rating results between the original and translated instrument, further evidence is needed to confirm whether the s-TOFHLA has the same or a different reliability within different cultures, thus assisting researchers to understand the generalisability of the s-TOFHLA's reliability results.

Six instruments were found to show satisfactory content validity and construct validity (i.e. structural validity, hypotheses testing and cross-cultural validity). Construct validity is a fundamental aspect of psychometrics and was examined for two reasons. First, it enables an instrument to be assessed for the extent to which operational variables adequately represent underlying theoretical constructs.⁵⁴ Second, the overall rating results of content validity for all instruments were similar. The only difference was that the target population was involved or not. Given that all instruments' items reflected the measured construct, in this review,

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4 construct validity was determined to be key to examining the overall validity of included
5 instruments. In this context, only the HLAT-8 showed positive evidence of structural validity
6 and hypotheses testing. However, in the original paper,⁴² the HLAT-8 was only tested for its
7 known-group validity, not for convergent validity. Examination of convergent validity is
8 important because it assists researchers in understanding the extent to which two examined
9 measures' constructs are theoretically and practically related.⁵⁵ Therefore, future research on
10 the convergent validity of the HLAT-8 would be beneficial for complementing that which
11 exists for its construct validity.
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18 As was the case in a previous study by Jordan *et al.*,²⁵ this review demonstrated that none of
19 the 15 studies contained evidence of responsiveness. Responsiveness is the ability of an
20 instrument to detect change over time in the construct being measured, and it is particularly
21 important for longitudinal studies.²⁸ However, most studies included in this review were
22 cross-sectional studies, and only one study (on the MMAHL⁴¹) discussed the potential to
23 measure health literacy over time. Studies that measure health literacy over time in
24 populations are needed, not only because this is a prerequisite for longitudinal studies, but
25 also so that the responsiveness of instruments can be monitored and improved.
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33 **Feasibility issues for included instruments**

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36 This review showed that the feasibility aspects of instruments varied markedly. In relation to
37 forms of administration, this review identified seven self-administered instruments and eight
38 interviewer-administered instruments. This suggests that both methods of administration are
39 well used. Self-administered instruments are cost-effective and efficient, but may bring about
40 respondent bias, whereas interviewer-administered instruments, while able to ensure high
41 response rates, are always resource intensive and expensive to administer.⁵⁶ Although the
42 literature showed that there was no significant difference in scores outcome between these
43 two administration modes,^{57 58} the relevant studies mostly concerned health-related quality of
44 life instruments. It is still unknown whether the same is true for health literacy instruments.
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46 Among children and adolescents, health literacy research is more likely to be conducted
47 through large-scale surveys in school settings. Therefore, the more cost-effective, self-
48 administered mode seems to have great potential for future research. To further support the
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4 wide use of self-administered instruments, there is a need for future research to confirm the
5 same effect of administration between self-administered and interviewer-administered
6 instruments.
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10 With regard to the type of assessment method, this review revealed that most health literacy
11 instruments for children and adolescents are performance-based. There might be two reasons
12 for this. First, it is due to participant characteristics. Compared with adults, children and
13 adolescents have limited cognitive ability and are dependent on their parents for health
14 decisions.¹⁴ It is challenging for them to accurately self-assess their ability to find, understand,
15 communicate and apply health information. Second, performance-based instruments are
16 objective, whereas self-report instruments are subjective and may bring about over-estimated
17 results.⁵⁹ However, the frequent use of performance-based instruments does not mean that
18 they are more appropriate than self-report instruments when measuring childhood and
19 adolescent health literacy. Compared with performance-based instruments, self-report
20 instruments are always time-efficient and help to preserve respondents' dignity.²⁰ The
21 challenge in using self-report instruments is to consider the readability of tested materials. If
22 children and adolescents can understand what a health literacy instrument measures, then
23 they can accurately self-assess their own health literacy skills.⁵² The difference between self-
24 report and performance-based instruments of health literacy has been discussed in the
25 literature,⁶⁰ but the evidence is still limited due to a lack of specifically-designed studies for
26 exploring the difference. Further studies are needed to fill this knowledge gap.
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39 **Recommendations for future research**

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42 This review identified ten instruments (the REALM-Teen, the NVS, the s-TOFHLA, the c-
43 sTOFHLAd, the eHEALS, the CHC Test, the HKACSS, the HLAB, the MHL, the HLAT-51)
44 that were used to measure health literacy in school settings. Although it is difficult to
45 categorically state which instrument is the best, this review provides useful information that
46 will assist researchers to identify the most suitable instrument to use when measuring health
47 literacy in children and adolescents in school contexts.
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4 Among the ten instruments, four tested functional health literacy (the REALM-Teen, the
5 NVS, the s-TOFHLA and the c-sTOFHLAd); one examined critical health literacy (the CHC
6 Test); one measured functional and interactive health literacy (the HKACSS); one examined
7 functional and critical health literacy (the HLAB); and three tested health literacy
8 comprehensively focusing on functional, interactive and critical domains (the eHEALS, the
9 MHL and the HLAT-51); however, none of these comprehensive instruments were
10 considered appropriate for use in schools. This was due to the fact that they focused on non-
11 general health literacy or were burdensome to administer. To ensure a three-domain nature
12 focus, only the MMAHL and the HLAT-8 were available for consideration in this review.
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20 After comparing measurement contexts and measurement purpose, the HLAT-8 was
21 identified as the most suitable instrument for measuring adolescent health literacy in school
22 settings for four reasons: (1) it measures health literacy in the context of family and friends,⁴²
23 a highly important attribute because children and adolescents often need support for health
24 decisions from parents and peers;^{7 14} (2) it is a short but comprehensive tool that captures
25 Nutbeam's three-domain nature of health literacy;¹⁶ (3) it showed satisfactory structural
26 validity (RMSEA=0.03; CFI=0.99; TLI=0.97; SRMR=0.03);⁴² and (4) it has good feasibility
27 (e.g. it is self-administered and time-efficient) for large-scale samples in school-based studies.
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35 **Limitations**

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38 This review was not without limitation. First, we restricted the search to studies aiming to
39 develop or validate a health literacy instrument. Thus we may have missed relevant
40 instruments in studies that were not aiming to develop instruments^{61 62} or the recently-
41 developed instruments.⁶³⁻⁶⁵ Second, although the COSMIN checklist provided us with strong
42 evidence of the methodological quality of a study via an assessment of each measurement
43 property, it cannot evaluate a study's overall methodological quality. Third, individual
44 subjectivity plays a part in the screening, data extraction and synthesis stage of the review. To
45 reduce this subjectivity, two authors independently managed the major stages.
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52 **CONCLUSION**

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4 This review updated previous reviews of childhood and adolescent health literacy
5 measurement and incorporated a quality assessment framework. It showed that most
6 information on measurement properties was unknown due to either the poor methodological
7 quality of studies or a lack of assessment and reporting. Rigorous and high-quality studies are
8 needed to fill the knowledge gap in relation to health literacy measurement in children and
9 adolescents. Although it is challenging to draw a robust conclusion about which instrument is
10 the best, this review provides important evidence that supports the use of the HLAT-8 to
11 measure childhood and adolescent health literacy in future school-based research.
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28 **CONTRIBUTORS**

29 SG conceived the review approach. RA and EW provided general guidance for the drafting of
30 the protocol. SG and SA screened the literature. SG and TS extracted data. SG drafted the
31 manuscript. SG, GB, RA and XY reviewed and revised the manuscript.
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40 or not-for-profit sectors.
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47 **COMPETING INTERESTS**

48 None.
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53 **DATA SHARING STATEMENT**

There are no additional data available.

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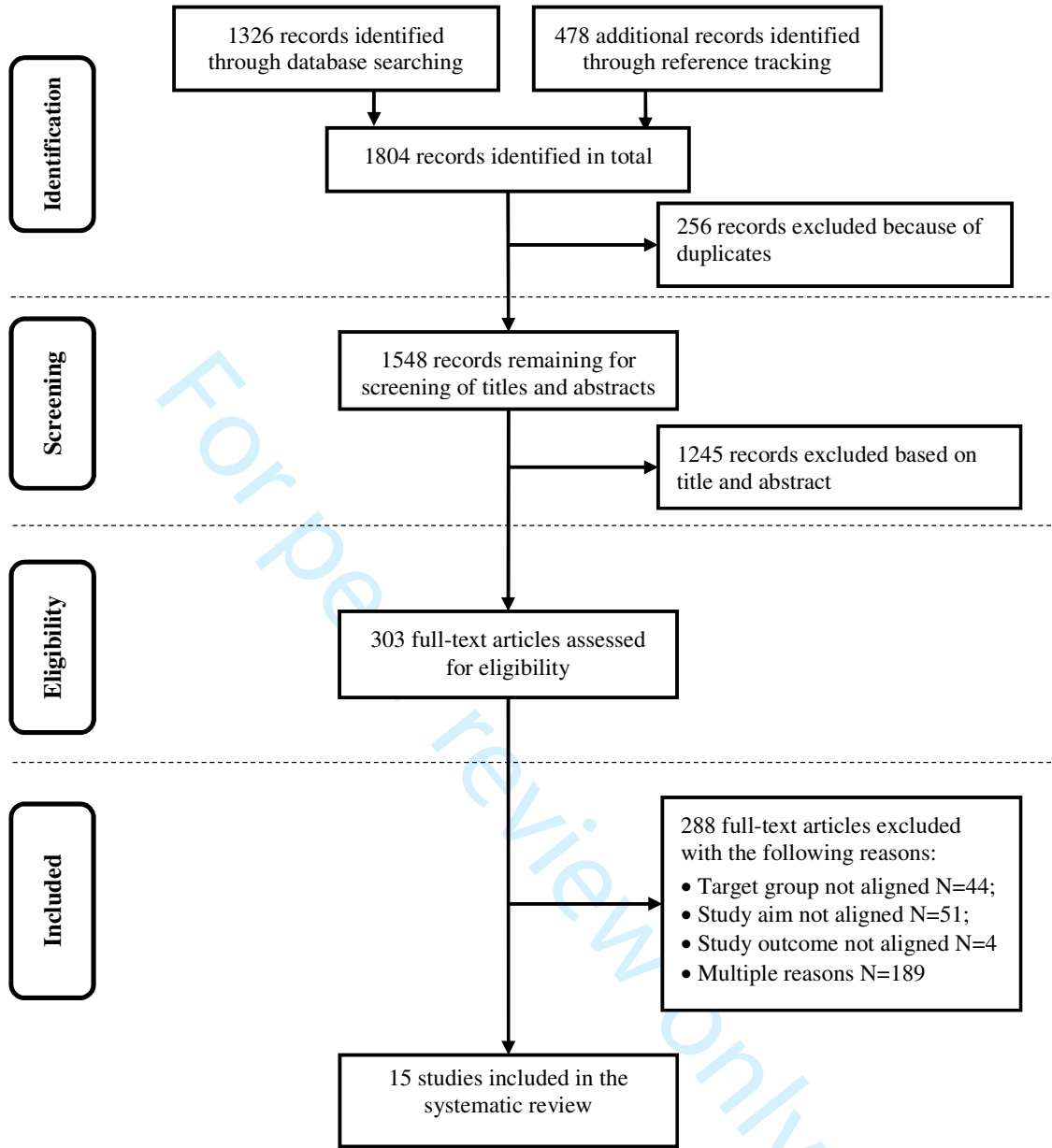


Figure 1. Flowchart of search and selection process according to PRISMA flow diagram

Appendix 1. A systematic review protocol

Measuring the Quality of Child and Adolescent Health Literacy Instruments: A Systematic Review

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Background

Health literacy research has been a growing interest by researchers across the globe. The term 'health literacy' was first used in 1974 in the proceedings of a health education conference discussing health education as a social policy issue affecting the healthcare system, mass communication and the education system (1, 2). However, few references were found regarding health literacy in the literature until 1992 (3). Since 1992, health literacy has been broadly studied both in clinical and public health contexts. In clinical settings, health literacy is typically defined as 'the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions' by the Institute of Medicine (IOM) in America (4). In such circumstances, health literacy is a derivative concept from literacy and numeracy skills, which is often used as a risk factor that needs to be identified and appropriately managed for patients and health professionals (5). Accordingly, health literacy measurement tools and 'screening aids' for clinicians are developed to assess patient literacy levels, and help health professionals to tailor health information for better communication with their patients (6). From the public health perspective, health literacy is defined and accepted by World Health Organization (WHO) as 'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health' (7). This understanding of health literacy identifies it as a broad concept, which is seen as a personal asset to enable individuals to take more control over their health and determinants of health (5). With a different understanding of the concept, health literacy measures vary in a different way. Although health literacy measurement varies and is still

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3 being debated (1, 8-10), there is consistent evidence showing health literacy is of potential
4 importance and considered as a public health goal internationally. A recent WHO report
5 pointed out that poor health literacy skills were associated with riskier behaviours, poorer
6 health status, less self-management and longer hospitalization and more health costs (11).
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10 Based on a preliminary search of health literacy, there were more interests in studies focusing
11 on adult health literacy than adolescent health literacy. However, previous research studies
12 suggested that poor health literacy was a prevalent problem in adolescents. In Australia, the
13 2006 National Health Literacy Survey reported that 67.6% of adolescents aged 15 to 19 years
14 old did not attain the minimum skills required to deal with health information and service in
15 everyday life (12). Compared with adult health literacy, there are several reasons for the
16 potential importance of adolescent health literacy: 1) adolescents are future mainstream and
17 independent healthcare consumers, a health literate person can contribute to less health care
18 costs, better health status compared to that is not health literate (13); 2) adolescents are at a
19 critical stage of development characterised by physical, emotional and cognitive changes,
20 attempting to prepare for independence but lacking the adequate ability of reasoning and
21 decision-making. Therefore, improving their health literacy skills could support sound health
22 decisions in future (14, 15); 3) low health literacy has been demonstrated to associate with
23 high levels of health-risk behaviors (16, 17) and low levels of health-promoting behaviors for
24 adolescents (18); 4) enhancing health literacy through school-based interventions has great
25 potential for improving students' access to and interpretation of health information (19).
26 Adolescents spend most of their daily time in school, which means they can receive health
27 education and learn how to improve healthy lifestyles and related skills through this setting
28 (20, 21).
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40 Health literacy is more challenging to understand for adolescents than that for adults.
41 Researchers may have different understandings and underlying constructs when using the
42 same definition. That is why there are such a large number of measurement tools of health
43 literacy currently (22, 23), along with some newly-developed health literacy instruments (24).
44 According to Mancuso (1), it is recommended to use specific assessment tools for a specific
45 age group in a specific context. Studies measuring childhood and adolescent health literacy
46 have been a research focus, particularly in the past five years (23). Ormshaw *et al.* (23)
47 conducted a systematic review on measuring childhood and adolescent health literacy in
48 2011. They found 16 studies that were involved with health literacy measures in children and
49 adolescents. The authors also identified 13 health topics and nine underlying components
50 from existing health literacy instruments. However, the authors did not critically appraise
51 health literacy indices explicitly regarding their validity and reliability. More importantly, the
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3 authors did not assess the methodological quality of each included study. This may undermine
4 the persuasiveness of its conclusion. To fill this knowledge gap, we aim to conduct a
5 systematic review that examines studies' methodological quality and examine reliability and
6 validity of each health literacy instrument, thus providing researchers with unbiased
7 information about which instruments have good psychometric properties. The '*CO*
8 *n*
9 *sensus-based Standards for the selection of health status Measurement INstruments*' (COSMIN)
10 group has recently developed as a critical appraisal tool (a checklist) to evaluate the
11 methodological quality of studies on measurement properties of health measurement
12 instruments (25). These measurement properties are divided into three domains: reliability,
13 validity, and responsiveness (26). According to the COSMIN checklist, it is possible and
14 scientific to critically appraise and compare psychometric properties of health literacy
15 instruments for children and adolescents.

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22 In this protocol, our target population is adolescent. According to the definition of the WHO,
23 adolescents are those people aged 10 to 19 years and young people aged 10-24 years (27, 28).
24 Given that the term '*adolescent*', '*child*', '*youth*' and '*young people*' is closely related, and
25 Erikson (29) reckoned that children between the ages of 6 and 12 years could learn, compete
26 and co-operate with others, we define our target group as those aged 6-24 years old.

30 31 **Objectives of the review**

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34 This review aims to identify which health literacy instruments have good psychometric
35 properties for children and adolescents. Specifically, there are three objectives:

- 36 1) To examine the methodological quality of included studies that aim to measure
37 health literacy in children and adolescents;
- 38 2) To examine the measurement properties (i.e. reliability; validity; responsiveness)
39 of health literacy instruments in children and adolescents;
- 40 3) To compare the overall rating of measurement properties between each health
41 literacy instrument used in children and adolescents.

42 43 44 45 46 47 **Search strategy**

48 49 50 ***Database and search terms***

51 As the term '*health literacy*' was first coined in 1974, articles published from 1st, January
52 1974 to 30th May 2014 in all languages will be searched. Search strategies will be first
53 designed and then be consulted with two librarian experts. Articles indexed in the following
54 seven databases: Medline, Pubmed, Embase, PsycINFO, CINAHL, ERIC and Cochrane

Library will be searched. The search key terms are ‘*health literacy*’ and ‘*assessment*’ according to previously published studies (1, 23, 30, 31). Age group for ‘*child, adolescent and young adult*’ will be defined in the database settings. The synonyms are listed in **Appendix Table 1**. These synonyms are connected by ‘*or*’ and search strategies are completed by ‘*and*’.

Appendix Table 1 Searching terms in databases

Key term (1)	Key term (2)
health literacy	health literacy measur*
health AND literacy AND education	health literacy assess*
	health literacy evaluat*
	health literacy instrument*
	health literacy tool*

Other sources of literature

Searching other sources to identify relevant research including:

- Reference lists of identified studies;
- Reference lists of previous systematic reviews on health literacy (1, 23, 30-33).

Eligibility criteria for inclusion and exclusion

According to the guidelines recommended by Cochrane Handbook for systematic reviews (34), inclusion criteria will be addressed regarding population, intervention, comparison, outcome and study design (PICOS):

Inclusion criteria-Participants

The target group should be children and/or adolescents, any age from 6 to 24 years of age.

Inclusion criteria-Interventions and Comparators

As interventional studies are not our interest in this review, it is not applicable to set out guidelines for interventions and comparators

Inclusion criteria-Outcomes

The included studies must be involved with health literacy assessment for children and adolescents, that is, the study should specify the term ‘*health literacy*’, and studies are included if they report on at least one or more attributes of the three measurement properties: 1) reliability; 2) validity; and 3) responsiveness.

Inclusion criteria-Study design

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3 The article should be research-based and peer-reviewed paper including study aim, methods,
4 and results. Also, the study aim should focus on health literacy instrument development or
5 validation.
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8 ***Exclusion criteria***

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10 Studies will be excluded if they are: 1) not focusing on the target group; 2) not focusing on
11 the health literacy instrument development or tool validation; 3) not research-based and peer-
12 reviewed papers including editorials, comments and letters; 4) not reporting findings or
13 results regarding any one of the measurement properties.
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16 **Study selection**

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18 Search records will be kept including the names of databases searched, keywords, search
19 timeframe, and the search results. All the electronic search results will be initially inputted
20 into the bibliography software of EndNote X7 (Thomson Reuters, New York, NY), and other
21 sources of literature results will be summarised in the print paper. This screening process will
22 follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)
23 statement (35). One reviewer will screen studies by titles and abstracts. Secondly, full copies
24 of articles identified will be obtained for thorough screening according to the inclusion
25 criteria by two reviewers independently. Any disagreements in reviewer selections will be
26 resolved at a meeting.
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34 **Quality assessment**

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36 The methodological quality of each included study will be assessed by two reviewers
37 independently using the COSMIN checklist (25). The checklist consists of nine boxes with 5-
38 18 items concerning methodological standards for how each measurement property should be
39 assessed. Four response options for each item of the COSMIN checklist are defined,
40 representing 'excellent', 'good', 'fair' and 'poor' quality. An overall score for the
41 methodological quality of a study will be determined for each measurement property
42 separately, by taking the lowest rating of any items in a box ('worst score counts') (36).
43 Discrepancies arise between the reviewers will be resolved through discussion, if necessary
44 with a third independent person.
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53 **Data extraction**

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55 Data extraction will be performed along with the assessment of methodological quality using
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3 the COSMIN checklist (25). In addition, information on the interpretability (e.g. norm scores,
4 floor-ceiling effects, minimal important change of the instruments), generalisability (e.g.
5 characteristics of the study population and sampling procedure), respondent and
6 administrative burden, and forms of administration will be also collected because they are
7 important characteristics of a measurement instrument (26, 37). The data will be entered in an
8 electronic form. Where possible, authors of the original studies will be contacted to obtain
9 essential missing or additional data. Two reviewers will independently extract the data.
10 Consensus should be reached afterward, if necessary with a third independent person.
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16 **Data synthesis**

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19 The results of the quality of health literacy instruments will be assessed using Terwee's
20 quality criteria (38), to see whether the results of the measurement attributes are 'positive',
21 'negative', or 'indeterminate'. To summarise the overall ratings of the measurement
22 properties of one health literacy instruments by different authors, the synthesis will be
23 performed by combining the results of the quality of health literacy instruments, the results of
24 methodological quality of health literacy measurement studies and the consistency of their
25 results. The possible overall rating for a measurement property is 'positive', 'indeterminate',
26 or 'negative', accompanied by levels of evidence, similarly as was proposed by the Cochrane
27 Back Review Group (39, 40). One reviewer will perform the data synthesis and a second
28 reviewer will check the synthesised results. Discrepancies of the results will be resolved by
29 discussion.
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Appendix 2. Search strategy for seven databases

1 MEDLINE (Web of Science) search strategy

MEDLINE database was searched using the Web of Science interface on 16/05/2014 for the period 1974 to 2014.

Basic search:

Set	Results	
# 1	500	<p>MeSH HEADING: (health literacy) <i>OR</i> ((TITLE: (health literacy) <i>OR</i> MeSH HEADING:exp: (Health Literacy)) <i>AND</i> (TITLE: (education) <i>OR</i> MeSH HEADING:exp: (Educational Status) <i>OR</i> MeSH HEADINGS:exp: (/education) <i>OR</i> MeSH HEADING:exp: (Teaching) <i>OR</i> MeSH HEADING:exp: (Educational Status) <i>OR</i> MeSH HEADING:exp: (Education)))</p> <p>Refined by: MeSH HEADINGS: (ADOLESCENT OR YOUNG ADULT OR CHILD) Indexes=MEDLINE Timespan=1974-2014</p>
# 2	3,880	<p>TOPIC: (((health) literacy assess* <i>OR</i> health literacy measur*) <i>OR</i> health literacy evaluat*) <i>OR</i> health literacy instrument*) <i>OR</i> health literacy tool*)</p> <p>Indexes=MEDLINE Timespan=1974-2014</p>
# 3	352	<p>#2 <i>AND</i> #1</p> <p>Indexes=MEDLINE Timespan=1974-2014</p>

2 PubMed search strategy

PubMed database was searched (Advanced search) on 16/05/2014 for the period 1974 to 16/05/2014.

Set	Results	
# 1	<u>4910</u>	Search (health literacy[MeSH Terms]) OR (health AND education AND literacy[Title/Abstract]) Sort by: PublicationDate
# 2	<u>3248385</u>	Search (child* OR adolescent* OR student* OR youth OR young people OR teen* OR young adult[Title/Abstract]) Sort by: PublicationDate Because if we select age group including child, adolescent, and young adult, the newest papers such as published in 2014 will not be included, the reason maybe the database doesn't update properly. So we use these terms to identify.
# 3	<u>1887</u>	Search (health literacy assess* OR health literacy measur* OR health literacy evaluat* OR health literacy instrument* OR health literacy tool*) Sort by: PublicationDate
# 4	<u>581</u>	Search (((health literacy[MeSH Terms]) OR (health AND education AND literacy[Title/Abstract]))) AND ((health literacy assess* OR health literacy measur* OR health literacy evaluat* OR health literacy instrument* OR health literacy tool*)) AND ((child* OR adolescent* OR student* OR youth OR young people OR teen* OR young adult[Title/Abstract])) Filters: Publication date from 1974/01/01 to 2014/05/16 Sort by: PublicationDate

3 EMBASE (Ovid) search strategy

EMBASE database was searched using Ovid interface on 16/05/2014 for the period 1974 to current.

Using .mp as searching terms (Advanced Search):

Set	Results	
#1	<u>6060</u>	("health literacy" or (health and literacy and education)).mp.
#2	<u>6043</u>	limit 1 to yr="1974 -Current"
#3	<u>671</u>	limit 2 to (school child <7 to 12 years> or adolescent <13 to 17 years>)
#4	<u>170</u>	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*).mp.
#5	<u>170</u>	limit 4 to yr="1974 -Current"
#6	<u>18</u>	3 and 5

4 PsycINFO (EBSCO) search strategy

PsycINFO database was searched using EBSCO interface on 16/05/2014 for the period January 1974 to May 2014.

Advanced Search:

Set	Results		
#1	<u>786</u>	health literacy OR (health AND literacy AND education)	Limiters - Published Date: 19740101-20140531; Age Groups: School Age (6-12 yrs), Adolescence (13-17 yrs), Young Adulthood (18-29 yrs) Search modes - Boolean/Phrase
#2	<u>133</u>	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Published Date: 19740101-20140531; Age Groups: School Age (6-12 yrs), Adolescence (13-17 yrs), Young Adulthood (18-29 yrs) Search modes - Boolean/Phrase
#3	<u>133</u>	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*) AND (S1 AND S2)	Search modes - Boolean/Phrase

5 CINAHL (EBSCO) search strategy

CINAHL database was searched using EBSCO interface on 16/05/2014 for the period January 1974 to May 2014.

Advanced Search:

Set	Results		
#1	<u>437</u>	health literacy OR (health AND education AND literacy)	Limiters - Published Date: 19740101-20140531; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase
#2	<u>63</u>	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Published Date: 19740101-20140531; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase
#3	<u>63</u>	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*) AND (S1 AND S2)	Search modes - Boolean/Phrase

6 ERIC (EBSCO) search strategy

ERIC database was searched using EBSCO interface on 16/05/2014 for the period January 1974 to May 2014.

Advanced Search:

Set	Results		
#1	<u>59</u>	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Date Published: 19740101-20140531 Search modes - Boolean/Phrase
#2	<u>2,250</u>	health literacy OR (health AND education AND literacy)	Limiters - Date Published: 19740101-20140531 Search modes - Boolean/Phrase
#3	<u>59</u>	S1 AND S2	Search modes - Boolean/Phrase

7 The Cochrane Library search strategy

The Cochrane Library database was searched on 30/05/2014 for the period January 1974 to May 2014.

Set	Results	Sub-database
#1	<u>4</u>	<p>Cochrane Reviews:</p> <p>There are 4 results from 8483 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Date from 1974 to 2014 in Cochrane Reviews'</p>
#2	<u>114</u>	<p>Trials:</p> <p>There are 114 results from 789657 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Date from 1974 to 2014 in Trials'</p>
#3	<u>2</u>	<p>Methods Studies:</p> <p>There are 2 results from 15764 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Date from 1974 to 2014 in Methods Studies'</p>
#4	<u>120</u>	

Appendix 3. Quality criteria for measurement properties of health literacy instruments

Property	Rating	Quality criteria	
Reliability			
Internal consistency	+	(Sub)scale unidimensional AND Cronbach's alpha(s) ≥ 0.70	
	?	Dimensionality not known OR Cronbach's alpha not determined	
	-	(Sub)scale not unidimensional OR Cronbach's alpha(s) < 0.70	
Measurement error	+	MIC > SDC OR MIC outside the LOA	
	?	MIC not defined	
Reliability	-	MIC \leq SDC OR MIC equals or inside LOA	
	+	ICC/weighted Kappa ≥ 0.70 OR Pearson's r ≥ 0.80	
	?	Neither ICC/weighted Kappa nor Pearson's r determined	
	-	ICC/weighted Kappa < 0.70 OR Pearson's r < 0.80	
Validity			
Content validity	+	The target population considers all items in the questionnaire to be relevant AND considers the questionnaire to be complete	
	?	No target population involvement	
	-	The target population considers items in the questionnaire to be irrelevant OR considers the questionnaire to be incomplete	
Construct validity			
	Structural validity	+	Factors should explain at least 50% of the variance
		?	Explained variance not mentioned
	-	Factors explain $< 50\%$ of the variance	
Hypotheses testing	+	(Correlation with an instrument measuring the same construct ≥ 0.50 OR at least 75% of the results are in accordance with the hypotheses) AND correlation with related constructs is higher than with unrelated constructs	
	?	Solely correlations determined with unrelated constructs	
	-	Correlation with an instrument measuring the same construct < 0.50 OR $< 75\%$ of the results are in accordance with the hypotheses OR correlation with related constructs is lower than with unrelated constructs	
Responsiveness			
Responsiveness	+	(Correlation with an instrument measuring the same construct ≥ 0.50 OR at least 75% of the results are in accordance with the hypotheses OR AUC ≥ 0.70) AND correlation with related constructs is higher than with unrelated constructs	
	?	Solely correlations determined with unrelated constructs	
	-	Correlation with an instrument measuring the same construct < 0.50 OR $< 75\%$ of the results are in accordance with the hypotheses OR AUC < 0.70 OR correlation with related constructs is lower than with unrelated constructs	

Note: AUC, Area Under the Curve; ICC, Intra-class Correlation Coefficient; LOA, Limits of Agreement; MIC, Minimal Important Change; SDC, Smallest Detectable Change. + positive rating; ? indeterminate rating; - negative rating.

Appendix 4. Levels of evidence for the overall rating of measurement properties

Level	Rating	Criteria
Strong	+++ or ---	Consistent findings in multiple studies of good methodological quality OR in one study of excellent methodological quality
Moderate	++ or --	Consistent findings in multiple studies of fair methodological quality OR in one study of good methodological quality
Limited	+ or -	One study of fair methodological quality
Conflicting	±	Conflicting findings
Unknown	?	Only studies of poor methodological quality

Note: + positive result; - negative result; ±conflicting result; ? unknown result.

For peer review only

Appendix 5. Reliability and validity results for included instruments

Appendix Table 2. The methodological quality of each study based on reliability for each health literacy instrument

Instrument	Internal consistency		Reliability			
	Result	COSMIN score	Result	Design	Time interval	COSMIN score
NVS (Warsh <i>et al.</i> , 2014)	na	na	na			na
NVS (Driessnack <i>et al.</i> , 2014)	$\alpha=0.71$ (n=47)	Poor	na			na
NVS (Hoffman <i>et al.</i> , 2013)	$\alpha=0.67$ (n=229)	Poor	na			na
c-sTOFHLAd (Chang <i>et al.</i> , 2012)	$\alpha=0.85$ (n=300) Item-total correlation=0.44-0.86	Fair	Correlation of test and retest was 0.95 ($P<0.001$)	Test-retest	1 week	Fair
TOFHLA (Chisolm and Buchanan, 2007)	na	na	na			na
s-TOFHLA (Hoffman <i>et al.</i> , 2013)	$\alpha=0.89$ (n=229)	Poor	na			na
REALM-Teen (Davis <i>et al.</i> , 2006)	$\alpha=0.94$ (n=388)	Poor	$\gamma=0.98$	Test-retest	1 week	Fair
REALM-Teen (Hoffman <i>et al.</i> , 2013)	$\alpha=0.92$ (n=229)	Poor	na			
HLAB (Wu <i>et al.</i> , 2010)	$\alpha=0.92$ (n=275) Understanding $\alpha=0.88$ (n=275) Evaluating $\alpha=0.82$ (n=275)	Fair	Concordance rate=95%	Inter-rater	na	Poor
MMAHL(Massey <i>et al.</i> , 2013)	$\alpha=0.83$ (n=1208) Item-total correlation=0.39-0.74	Good	na			na
MHL (Levin-Zamir <i>et al.</i> , 2011)	$\alpha=0.74$ (n=1316) Coefficient of reproducibility=0.84 Coefficients of scalability=0.54-0.80	Poor	na			na
DNT-39 (Mulvaney <i>et al.</i> , 2013)	$\alpha=0.93$ (n=61)	Fair	na			na
DNT-14 (Mulvaney <i>et al.</i> , 2013)	$\alpha=0.82$ (n=133) $\alpha=0.80$ (n=61)	Fair	na			na

Instrument	Internal consistency		Reliability			
	Result	COSMIN score	Result	Design	Time interval	COSMIN score
eHEALS (Norman and Skinner, 2006)	$\alpha=0.83$ (n=72) $\alpha=0.88$ (n=664) Item-scale correlation coefficient=0.51-0.76	Fair	The correlations between administrations ranged 0.68-0.40.	Test-retest	Immediately after the intervention; 3-month; 6-month	Fair
CHC Test (Steckelberg <i>et al.</i> , 2009)	na	na	Cohen's Kappa was excellent for 277 ratings ($\kappa=0.9-1.0$), moderate or good for 31 ratings ($\kappa=0.7-0.89$) and poor for 5 ratings ($\kappa<0.7$)	Inter-rater	na	Poor
HKACSS (Schmidt <i>et al.</i> , 2010)	Health knowledge $\chi^2=6.45$, $P=0.17$ (n=852) Health communication $\alpha=0.73$ (n=852) Health attitudes $\alpha=0.57$ (n=852)	Excellent	na			na
HLAT-51 (Harper, 2014)	Goodness of fit statistic was calculated by each domain (CFI=0.33-0.88; TLI=0.66-0.84; RMSEA=0.09-0.17). The internal consistency statistic was not calculated.	Poor	na			na
HLAT-8 (Abel <i>et al.</i> , 2014)	$\alpha=0.64$ (n=7097 for male) $\alpha=0.65$ (n=331 for female)	Excellent	na			na

Note: na, no information available. CFI, Comparative Fit Index; CHC Test, the Critical Health Competence Test; c-STOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; RMSEA, Root Mean Square Error of Approximation; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TLI, Tucker-Lewis Index; TOFHLA, the Test of Functional Health Literacy in Adults.

Appendix Table 3. The methodological quality of each study based on **validity** for each health literacy instrument

Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
1 NVS 12 (Warsh <i>et al.</i> , 13 2014)	A panel of health literacy experts developed the NVS according to previous experience. The NVS was then refined after feedback from patients, interviewers, and data analysts. No target population is involved in this study.	Poor	na	na	Hypotheses regarding correlation between scores of a comparator instrument of Gray Silent Reading Test (GSRT) and NVS were formulated before data collection. The NVS and GSRT scores were highly correlated ($\rho=0.71$, $p<0.0001$). The NVS score increased with child age ($\rho=0.53$, $p<0.0001$).	Fair	na	na
20 NVS 21 (Driessnack 22 <i>et al.</i> , 2014)	A panel of health literacy experts developed the NVS according to previous experience. The NVS was then refined after feedback from patients, interviewers, and data analysts. No target population is involved in this study.	Poor	na	na	A moderate positive correlation was found between children's NVS scores and their age, and between children's NVS scores and their reports of books numbers ($\gamma_s=0.43$, $p=0.003$; $\gamma_s=0.36$, $p=0.012$, respectively), but not found with their parents' report of the number of children's books at home ($\gamma_s=0.06$, $p=0.671$).	Poor	na	na
30 NVS 31 (Hoffman <i>et al.</i> , 2013)	A panel of health literacy experts developed the NVS according to previous experience. The NVS was then refined after feedback from patients, interviewers, and data analysts. No target population is involved in this study.	Poor	na	na	Convergent validity was measured between NVS and the TerraNova academic achievement test, with a correlation coefficient of 0.49 ($p<0.01$).	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
	this study.							
c-TOFHLAd (Chang <i>et al.</i> , 2012)	The c-sTOFHLAd was translated from the short-version of TOFHLA according to translation procedures and was tested among 30 adolescents to ensure appropriateness.	Good	Confirmatory factor analysis was conducted to determine structural validity. One-factor model indicated an acceptable fit to the data according structural equation modelling analysis.	Fair	Convergent validity was measured between c-sTOFHLAd and the rapid estimate of adult literacy in medicine (REALM), with a correlation coefficient of 0.74 ($p<0.001$).	Fair	Semantic equivalence was measured by the content validity index (CVI). All items were rated by the experts as having a CVI>0.85. Thirty adolescents were chosen to determine and ensure the cultural congruence of the instrument.	Fair
TOFHLA (Chisolm and Buchanan, 2007)	The TOFHLA was developed from a literacy expert after reviewing commonly used hospital texts and a pilot test. No target population is involved in this study.	Poor	na	na	The reading comprehension component (TOFHLA-R) was significantly collated with the Wide-Ranging Achievement Test (WRAT3) and the rapid estimate of adult literacy in medicine (REALM) ($\rho=0.59$, $p<0.001$; $\rho=0.60$, $p<0.001$ respectively), however, no correlation were found with the numeracy component (TOFHLA-N) ($\rho=0.11$, $p=0.45$; $\rho=0.18$, $p=0.22$ respectively).	Fair	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013)	The s-TOFHLA was developed based on previous data analysis, perceived importance and frequency of the task in the healthcare settings.	Poor	na	na	Convergent validity was measured between NVS and the TerraNova academic achievement test, with a correlation coefficient of 0.28 ($p<0.01$).	Fair	na	na
REALM-Teen	The REALM-Teen was	Good	na	na	Convergent validity was	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity		
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	REALM-Teen (Davis <i>et al.</i> , 2006)	developed based on a preliminary test and a structured interview among adolescents. And a panel of experts reviewed the word list.	Poor	na	na	Convergent validity was measured between REALM-Teen and the WRAT-3 ($r=0.83$) and SORT-R ($r=0.93$).	Poor	na	na
32 33 34 35 36 37 38	HLAB (Wu <i>et al.</i> , 2010)	Previous experience and literature review were used to develop items; 10 students were pilot-tested for appropriateness of wording, content and format of the final instrument.	Good	na	na	Correlations were assumed between socio-demographic variables and the overall scores. Socio-demographics of gender, age when came to Canada to live, speaking a language other than English were correlated with the scores of HLAB ($\beta=-0.18$, $p=0.004$; $\beta=-0.22$, $p=0.014$; $\beta=-0.20$, $p=0.008$ respectively). No convergent validity is assessed.	Fair	na	na
39 40 41 42 43 44 45 46 47	MMAHL (Massey <i>et al.</i> , 2013)	Domains were established from literature review and focus group. Items were developed either using adaptation of existing relevant items or created by the research team.	Good	Explorative principal components factor analysis was conducted and 49.8% of the variance was accounted by 6 factors.	Good	na	na	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
MHL (Levin-Zamir <i>et al.</i> , 2011)	The face validity was discussed in the focus group during pilot test. The content validity was analysed using theory and operational definitions of health literacy and media literacy, and adolescents were invited to write detailed, anonymous responses.	Good	na	na	As hypothesised, MHL was associated with socio-economic determinants, particularly with gender ($\beta=1.25$, $p<0.001$) and mother's education ($\beta=0.16$, $p=0.04$). In addition, MHL was also associated with health behaviours ($\beta=0.03$, $p=0.05$) and health empowerment ($\beta=0.36$, $p<0.001$).	Good	na	na
DNT-39 (Mulvaney <i>et al.</i> , 2013)	The DNT-39 was developed from the original 43-item version DNT-43 by eliminating questions specific to type 2 diabetes. An expert team developed the DNT-43 and refined it.	Poor	na	na	The DNT-39 was associated with WRAT-3 and parent education ($\rho=0.40$, $p=0.001$; $\rho=0.29$, $p=0.028$ respectively)	Fair	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013)	The DNT-14 was developed from the original 15-item version DNT-15 by eliminating 1 question specific to type 2 diabetes. An expert team developed the DNT-15 by data analysis from DNT-43.	Poor	na	na	The DNT-14 was associated with the Wide-Ranging Achievement Test (WRAT3), parent education, diabetes problem solving and HbA1c ($\rho=0.36$, $p=0.005$; $\rho=0.31$, $p=0.019$; $\rho=0.27$, $p=0.023$; $\rho=-0.34$, $p=0.004$ respectively)	Fair	na	na
eHEALS (Norman and Skinner, 2006)	The eHEALS was developed by the expert team and pilot-tested and refined by feedback from	Good	Explorative principal components factor analysis was conducted and 56% of the	Fair	Correlations were assumed between eHEALS and other measured variables (gender, age, use of information technology	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
	participants.		variance was accounted by a single factor. The factor loadings ranged from 0.60-0.84 among the 8 items.		overall, self-evaluations of health). However, only gender difference was found at baseline level of eHealth literacy (t=2.236, p=0.026). No convergent validity is assessed.			
CHC Test (Steckelberg <i>et al.</i> , 2009)	The CHC Test was developed by the research team and pre-tested by collecting qualitative data and quantitative field test.	Good	IRT test for determining dimensionality was performed.	Poor	na	na	na	na
HKACSS (Schmidt <i>et al.</i> , 2010)	The HKACSS items were taken from a previous health survey and selected basing on consideration of item content.	Good	na	na	As hypothesised, health communication, attitudes and self-efficacy were significantly related to each other ($\rho=0.15-0.38$, $P<0.05$). And children from higher educational background showed a better knowledge and communicated more about health topics ($\beta=0.16$, $p<0.05$).	Good	na	na
HLAT-51 (Harper, 2014)	The expert team evaluated the initial items using a 5-point Likert scale according to their research experience. And 144 college students were invited to complete a pilot test.	Good	Comprehension (CFI=0.80; TLI=0.78; RMSEA=0.09); health numeracy (CFI=0.57; TLI=0.48; RMSEA=0.09); media literacy (CFI=0.88; TLI=0.84; RMSEA=0.07); digital literacy (CFI=0.33; TLI=0.06;	Poor	na		na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity		
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	
HLAT-8 (Abel <i>et al.</i> , 2014)	The research team developed the HALT-8 drawing on literature review and their own experience. No target population is involved in this study.	Poor	Explorative principal components factor analysis was conducted and 72.96% of the variance was accounted by four factors among male. In addition, the factor structure was validated using confirmatory factor analysis (CFI=0.99; TLI=0.97; RMSEA=0.03; SRMR=0.03).	Excellent	RMSEA=0.16); health information seeking (CFI=0.80; TLI=0.66; RMSEA=0.17)	Hypotheses were formulated a priori regarding correlations between health literacy and gender, socio-cultural characteristics and health values. Results showed that female, higher educational status, and a stronger health valuation were associated with higher HL scores ($p<0.05$, respectively).	Good	na	na

Note: na, no information available. CFI, Comparative Fit Index; CHC Test, the Critical Health Competence Test; c-sTOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; RMSEA, Root Mean Square Error of Approximation; SRMR, Standardized Root Mean Square Residual; SORT-R, Slosson Oral Reading Test-Revised; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TLI, Tucker-Lewis Index; TOFHLA, the Test of Functional Health Literacy in Adults; WRAT-3, Wide-Range Achievement Test-Revised.

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Research Checklist. PRISMA checklist for reporting systematic review

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-7
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	7
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Appendix 1
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8
Data collection process	10	Describe <u>method</u> of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	9-10

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	9-10
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	10; Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	10; 13-14; Table 1 & 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	19; Table 3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	19; Table 4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	19; Table 5
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	19; Table 5
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	23-28
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	28
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	28-29
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

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The Quality of Health Literacy Instruments used in Children and Adolescents: A Systematic Review

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ABSTRACT

Objective: Improving health literacy at an early age is crucial to personal health and development. Although health literacy in children and adolescents has gained momentum in the past decade, it remains an under-researched area, particularly health literacy measurement. This study aimed to examine the quality of health literacy instruments used in children and adolescents and to identify the best instrument for field use.

Design: Systematic review.

Setting: A wide range of settings including schools, clinics and communities.

Participants: Children and/or adolescents aged 6-24 years.

Primary and secondary outcome measures: Measurement properties (reliability, validity and responsiveness) and other important characteristics (e.g. health topics, components or scoring systems) of health literacy instruments.

Results: There were 29 health literacy instruments identified from the screening process. When measuring health literacy in children and adolescents, researchers mainly focus on the functional domain (basic skills in reading and writing) and consider participant characteristics of developmental change (of cognitive ability), dependency (on parents) and demographic patterns (e.g. racial/ethnic backgrounds), less on differential epidemiology (of health and illness). The methodological quality of included studies as assessed via measurement properties varied from poor to excellent. More than half (62.9%) of measurement properties were unknown, due to either poor methodological quality of included studies or a lack of reporting or assessment. The 8-item Health Literacy Assessment Tool (HLAT-8) showed best evidence on construct validity and the Health Literacy Measure for Adolescents showed best evidence on reliability.

Conclusions: More rigorous and high-quality studies are needed to fill the knowledge gap in measurement properties of health literacy instruments. Although it is

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3 challenging to draw a robust conclusion about which instrument is the most reliable
4 and the most valid, this review provides important evidence that supports the use of
5 the HLAT-8 to measure childhood and adolescent health literacy in future school-
6 based research.
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11 **Keywords:** measurement properties; health literacy; children; adolescents; systematic
12 review
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For peer review only

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The COSMIN checklist was used as a methodological framework to rate the methodological quality of included studies.
- This review has updated previous three reviews of childhood and adolescent health literacy measurement tools and identified 19 additional new health literacy instruments.
- Including only studies that aimed to develop or validate a health literacy instrument may eliminate studies that used a health literacy instrument for other purposes.
- Individual subjectivity exists in the screening and data synthesis stages.

INTRODUCTION

Health literacy is a personal resource that enables an individual to make decisions for healthcare, disease prevention and health promotion in everyday life.¹ As defined by the World Health Organisation,² health literacy refers to ‘*the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health.*’ The literature has shown that health literacy is an independent and more direct predictor of health outcomes than socio-demographics.^{3 4} People with low health literacy are likely to have worse health-compromising behaviours, higher healthcare costs and poorer health status.⁵ Given the close relationship between health literacy and health outcomes, many countries have adopted health literacy promotion as a key strategy to reduce health inequities.⁶

From a health promotion perspective, improving health literacy at an early age is crucial to childhood and adolescent health and development.⁷ As demonstrated by Diamond *et al.*⁸ and Robinson *et al.*,⁹ health literacy interventions for children and adolescents can bring about improvements in healthy behaviours and decreased use of emergency department services. Although health literacy in young people has gained increasing attention, with a rapidly growing number of publications in the past decade,¹⁰⁻¹³ childhood and adolescent health literacy is still under-researched. According to Forrest *et al.*'s 4D model,^{14 15} health literacy in children and adolescents is mediated by four additional factors compared to adults: (1) *developmental* change: children and adolescents have less well-developed cognitive ability than adults; (2) *dependency*: children and adolescents depend more on their parents and peers than adults do; (3) *differential* epidemiology: children and adolescents experience a unique pattern of health, illness and disability; and (4) *demographic* patterns: many children and adolescents living in poverty or in single-parent families are neglected and so require additional care. These four differences pose significant challenges for researchers when measuring health literacy in children and adolescents.

Health literacy is a broad and multi-dimensional concept with varying definitions.¹⁶ This paper uses the definition by Nutbeam who states that health literacy consists of three domains: functional, interactive and critical.¹⁷ The *functional* domain refers to

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3 basic skills in reading and writing health information, which are important for
4 functioning effectively in everyday life. The *interactive* domain represents advanced
5 skills that allow individuals to extract health information and derive meaning from
6 different forms of communication. And the *critical* domain represents more advanced
7 skills that can be used to critically evaluate health information and take control over
8 health determinants.¹⁷ Although health literacy is sufficiently explained in terms of its
9 definitions¹⁷⁻¹⁹ and theoretical models,^{4,7} its measurement remains a contested issue.
10 There are two possible reasons for this. One reason is the large variety of health
11 literacy definitions and conceptual models,^{12,16} and the other reason is that researchers
12 may have different study aims, populations and contexts when measuring health
13 literacy.^{20,21}

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22 Currently, there are three systematic reviews describing and analysing the
23 methodology and measurement of childhood and adolescent health literacy.^{10,11,13} In
24 2013, Ormshaw *et al.*¹⁰ conducted a systematic review of child and adolescent health
25 literacy measures. This review used four questions to explore health literacy
26 measurement in children and adolescents: “*What measurement tools were used? What*
27 *health topics were involved? What components were identified? and Did studies*
28 *achieve their stated aims?*” The authors identified 16 empirical studies, with only six
29 of them evaluating health literacy measurement as their primary aim. The remaining
30 studies used health literacy measures as either a comparison tool when developing
31 other new instruments or as a dependent variable to examine the effect of an
32 intervention program. Subsequently, in 2014, Perry¹¹ conducted an integrative review
33 of health literacy instruments used in adolescents. In accordance with the eligibility
34 criteria, five instruments were identified. More recently, Okan *et al.*¹³ conducted
35 another systematic review on generic health literacy instruments used for children and
36 adolescents with the aim of identifying and assessing relevant instruments for first-
37 time use. They found fifteen generic health literacy instruments used for this target
38 group.

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51 Although these three reviews provide general knowledge about the methodology and
52 measurement of health literacy in young people, they all have limitations. Ormshaw *et*
53 *al.*¹⁰ did not evaluate measurement properties of each health literacy instrument.
54 Although Perry¹¹ and Okan *et al.*¹³ summarised measurement properties of each
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3 instrument, the information provided was limited, mostly descriptive, and lacked a
4 critical appraisal. Notably, none of the three reviews considered the methodological
5 quality of included studies^{10 11 13}. A lack of quality assessment of studies raises
6 concerns about the utility of such reviews for evaluating and selecting health literacy
7 instruments for children and adolescents. Therefore, it is still unclear which
8 instrument is the best in terms of its validity, reliability and feasibility for field use. In
9 addition, it is also unclear how Nutbeam's three-domain health literacy model and
10 Forrest *et al.*'s 4D model are considered in existing health literacy instruments for
11 children and adolescents.
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19 To fill these knowledge gaps, this systematic review aimed to examine the quality of
20 health literacy instruments used in the young population and to identify the best
21 instrument for field use. We expect the findings will assist researchers in identifying
22 and selecting the most appropriate instrument for different purposes when measuring
23 childhood and adolescent health literacy.
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28 **METHODS**

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32 Following the methods for conducting systematic reviews outlined in the Cochrane
33 Handbook,²² we developed a review protocol (See **Appendix 1**, PROSPERO
34 registered ID: CRD42018013759) prior to commencing the study. The Preferred
35 Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement²³
36 (See **Research Checklist**) was used to ensure the reporting quality of this review.
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41 **Literature search**

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45 The review took place over two time periods: The initial systematic review covered
46 the period between 1 January 1974 and 16 May 2014 (period 1). The start date of
47 1974 was chosen because this was the date from which the term '*health literacy*' was
48 first used.²⁴ A second search was used to update the review in February 2018. It
49 covered the period 17 May 2014 to 31 Jan 2018 (period 2). The databases searched
50 were: Medline, PubMed, Embase, PsycINFO, CINAHL, ERIC and the Cochrane
51 Library. The search strategy was designed on the basis of previous reviews^{5 10 25 26} and
52 in consultation with two librarian experts. Three types of search terms were used: (1)
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3 construct-related terms: ‘*health literacy*’ OR ‘*health and education and literacy*’; (2)
4 outcome-related terms: ‘*health literacy assess**’ OR ‘*health literacy measure**’ OR
5 ‘*health literacy evaluat**’ OR ‘*health literacy instrument**’ OR ‘*health literacy tool**’;
6 and (3) age-related terms: ‘*child**’ OR ‘*adolescent**’ OR ‘*student**’ OR ‘*youth*’ OR
7 ‘*young people*’ OR ‘*teen**’ OR ‘*young adult.*’
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12 No language restriction was applied. The detailed search strategy for each database is
13 available in **Appendix 2**. As per the PRISMA flow diagram,²³ the references from
14 included studies and from six previously published systematic reviews on health
15 literacy^{5 10 25-28} were also included.
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19 20 **Eligibility criteria**

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22 Studies had to fulfil the following criteria to be included: (1) the stated aim of the
23 study was to develop or validate a health literacy instrument; (2) participants were
24 children or adolescents aged 6 to 24. This broad age range was used because the age
25 range for ‘*children*’ (under the age of 18) and ‘*adolescents*’ (aged 10 to 24) overlap²⁹
26 and also because children aged over 6 are able to learn and develop their own health
27 literacy³⁰; (3) the term ‘*health literacy*’ was explicitly defined, although studies
28 assessing health numeracy (the ability to understand and use numbers in healthcare
29 settings) were also considered; and (4) at least one measurement property (reliability,
30 validity and responsiveness) was reported in the outcomes.
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39 Studies were excluded if: (a) the full paper was not available (i.e. only a conference
40 abstract or protocol was available); (b) they were not peer-reviewed (e.g. dissertations,
41 government reports); or (c) they were qualitative studies.
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46 **Selection process**

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48 All references were imported into EndNote X7 software (Thomson Reuters, New
49 York, NY) and duplicate records were initially removed before screening. Next, one
50 author (GS) screened all studies based on title and abstract. Full-text papers of the
51 remaining titles and abstracts were then obtained separately for each review round
52 (period 1 and period 2). All papers were screened by two independent authors (GS
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and SA). At each major step of this systematic review, discrepancies between authors were resolved through discussion.

Data extraction

The data that were extracted from papers were: characteristics of included studies (e.g. first author, published year and country), general characteristics of instruments (e.g. health topics, components and scoring systems), methodological quality of the study (e.g. internal consistency, reliability and measurement error) and ratings of measurement properties of included instruments (e.g. internal consistency, reliability and measurement error). Data extraction from full-text papers published during period 1 was performed by two independent authors (GS and TS), whereas data extraction from full-text papers published during period 2 was conducted by one author (GS) and then checked by a second author (TS).

Methodological quality assessment of included studies

The methodological quality of included studies was assessed using the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist.³¹ The COSMIN checklist is a critical appraisal tool containing standards for evaluating the methodological quality of studies on measurement properties of health measurement instruments.³² Specifically, nine measurement properties (internal consistency, reliability, measurement error, content validity, structural validity, hypotheses testing, cross-cultural validity, criterion validity and responsiveness) were assessed.³² Since there is no agreed-upon ‘gold standard’ for health literacy measurement,^{33 34} criterion validity was not assessed in this review. Each measurement property section contains 5 to 18 evaluating items. For example, ‘internal consistency’ is evaluated against 11 items. Each item is scored using a four-point scoring system (‘excellent’, ‘good’, ‘fair’ or ‘poor’). The overall methodological quality of a study is obtained for each measurement property separately, by taking the lowest rating of any item in that section (i.e. ‘worst score counts’). Two authors (GS and TS) independently assessed the methodological quality of included studies published during period 1, whereas the quality of included

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3 studies published during period 2 was assessed by one author (GS) and then checked
4 by another (TS).
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7 8 **Evaluation of measurement properties for included instruments**

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10 The quality of each measurement property of an instrument was evaluated using
11 quality criteria proposed by Terwee *et al.*³⁵, who are members of the group that
12 developed the COSMIN checklist (See **Appendix 3**). Each measurement property was
13 given a rating result ('+' positive, '-' negative, '?' indeterminate and 'na' no
14 information available).
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19 20 **Best evidence synthesis: levels of evidence**

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22 As recommended by the COSMIN checklist developer group,³² '*a best evidence*
23 *synthesis*' was used to synthesise all the evidence on measurement properties of
24 different instruments. The procedure used was similar to the Grading of
25 Recommendations, Assessment, Development and Evaluation (GRADE) framework³⁶,
26 a transparent approach to rating quality of evidence that is often used in reviews of
27 clinical trials.³⁷ Given that this review did not target clinical trials, the GRADE
28 framework adapted by the COSMIN group was used.³⁸ Under this procedure, the
29 possible overall rating for a measurement property is '*positive*', '*negative*',
30 '*conflicting*' or '*unknown*', accompanied by levels of evidence ('*strong*', '*moderate*'
31 or '*limited*') (See **Appendix 4**). Three steps were taken to obtain the overall rating for
32 a measurement property. First, the methodological quality of a study on each
33 measurement property was assessed using the COSMIN checklist. Measurement
34 properties from '*poor*' methodological quality studies did not contribute to '*the best*
35 *evidence synthesis*'. Second, the quality of each measurement property of an
36 instrument was evaluated using Terwee's quality criteria.³⁵ Third, the rating results of
37 measurement properties in different studies on the same instrument were examined
38 whether consistent or not. This best evidence synthesis was performed by one author
39 (GS) and then checked by a second author (TS).
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54 55 **Patient and Public Involvement**

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3 Children and adolescents were not involved in setting the research question, the
4 outcome measures, or the design or implementation of this study.
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7 8 **Results**

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11 The initial search identified 2790 studies. After duplicates and initial title/abstract
12 screening, 361 full-text articles were identified and obtained. As per the eligibility
13 criteria, 29 studies were included,³⁹⁻⁵³ yielding 29 unique health literacy instruments
14 used in children and adolescents (See **Figure 1**).
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18 19 **Characteristics of included studies**

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22 Of the 29 studies identified, 25 were published between 2010 and 2017 (See **Table 1**).
23 Most included studies were conducted in Western countries (n=20), with eleven
24 studies carried out in the USA. The target population (aged 7 to 25) could be roughly
25 classified into three subgroups: children aged 7 to 12 (n=5), adolescents aged 13 to 17
26 (n=20) and young adults aged 18 to 25 (n=4). Schools (n=17) were the most common
27 recruitment settings, compared to clinical settings (n=8) and communities (n=4).
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Table 1. Characteristics of included studies

Study no	Author (Year)	Country	Target population	Health literacy instrument	Sample size (% male)	Sampling method	Recruitment setting
1	Davis <i>et al.</i> ⁴¹ (2006)	USA	Adolescents aged 10-19 years (mean age=14.8±1.9)	REALM-Teen	1533 (47.4)	na	Middle schools, high schools, paediatric primary care clinic and summer programs
2	Norman and Skinner ⁴³ (2006)	Canada	Adolescents aged 13-21 years (mean age=14.95±1.24)	eHEALS	664 (55.7)	Sampling from one arm of a randomized controlled trial	Secondary schools
3	Chisolm and Buchanan ⁴⁸ (2007)	USA	Young people aged 13-17 years (mean age=14.7)	TOFHLA	50 (48.0)	na	Children's hospital
4	Steckelberg <i>et al.</i> ⁴⁷ (2009)	Germany	Students in Grade 10-11 and university	CHC Test	Sample 1: 322 (36.6) Sample 2: 107 (32.7)	na	Secondary schools, university
5	Schmidt <i>et al.</i> ⁴⁶ (2010)	Germany	Children aged 9-13 years (mean age=10.4)	HKACSS	852 (52.9)	na	Primary school
6	Wu <i>et al.</i> ⁴⁰ (2010)	Canada	Students in Grade 8-12	HLAB	275 (48.0)	Convenience sampling	Secondary schools
7	Levin-Zamir <i>et al.</i> ⁴⁹ (2011)	Israel	Adolescents in Grade 7, 9, 11 (approximately age 13, 15 and 17)	MHL	1316 (52.0)	Probability sampling and random cluster sampling	Public schools
8	Chang <i>et al.</i> ⁵¹ (2012)	Taiwan	Students in high school (mean age=16.01±1.02)	c-sTOFHLAd	300 (52.6)	Multiple-stage stratified random sampling	High schools
9	Hoffman <i>et al.</i> ⁵⁰ (2013)	USA	Youth aged 14-19 years (mean age=17)	REALM-Teen; NVS; s-TOFHLA	229 (61.6)	na	Private high school
10	Massey <i>et al.</i> ⁴⁴ (2013)	USA	Adolescents aged 13-17 years (mean age=14.8)	MMAHL	1208 (37.6)	Sampling from a large health insurance network	Publicly health insurance network
11	Mulvaney <i>et al.</i> ⁵³ (2013)	USA	Adolescents aged 12-17 years (Sample 1: mean age=13.92; Sample 2: mean age=15.10)	DNT-39 and DNT-14	Sample 1: 61 (52.5) Sample 2: 72 (55.6)	na	Diabetes clinics

Study no	Author (Year)	Country	Target population	Health literacy instrument	Sample size (% male)	Sampling method	Recruitment setting
12	Abel <i>et al.</i> ⁴⁵ (2014)	Switzerland	Young adults aged 18-25 years (male mean age: 19.6; female mean age=18.8)	HLAT-8	7428 (95.5)	Sampling from compulsory military service for males and two-stage random sampling for females	Compulsory military service, communities
13	Driessnack <i>et al.</i> ⁵⁴ (2014)	USA	Children aged 7-12 years	NVS	47 (53.0)	Convenience sampling	The science centre
14	Harper ⁴² (2014)	New Zealand	Students aged 18-24 years	HLAT-51	144 (41.0)	Purposeful sampling	College
15	Warsh <i>et al.</i> ³⁹ (2014)	USA	Children aged 7-17 years (median age=11)	NVS	97 (46.0)	Convenience sampling	Paediatric clinics
16	Liu <i>et al.</i> ⁵⁵ (2014)	Taiwan	Children in grade six	CHLT	162609 (51.1)	National sampling	Primary schools
17	Ueno <i>et al.</i> ⁵⁶ (2014)	Japan	Students in high school Grade 1 (age range: 15-16 years)	VOHL	162 (46.3)	Convenience sampling	A senior high school
18	Manganello <i>et al.</i> ⁵⁷ (2015)	USA	Youth aged 12-19 years (mean age=15.6)	HAS-A	272 (37.0)	Convenience sampling	A paediatric clinic and the community
19	Naigaga <i>et al.</i> ⁵⁸ (2015)	Uganda	Pregnant adolescents aged 15-19 years	MaHeLi	384 (0)	Random sampling	Health centres
20	de Jesus Loureiro <i>et al.</i> ⁵⁹ (2015)	Portugal	Adolescents and young people aged 14-24 years (mean age=16.75±1.62)	QuALiSMental	4938 (43.3)	Multi-stage cluster random sampling	Schools
21	McDonald <i>et al.</i> ⁶⁰ (2016)	Australia	Adolescents and young adults diagnosed with cancer (age range: 12-24 years)	FCCHL-AYAC	105 (33.3)	Sampling from a support organisation	An organisation for young people living with cancer
22	Smith <i>et al.</i> ⁶¹ (2016)	USA	Deaf/hard-of hearing and hearing adolescents in high school (mean age=17.0±0.84 and 15.8±1.1)	ICHL	Sample 1: 154 (53.2) Sample 2: 89 (33.0)	Convenience sampling	Medical centre summer programs
23	Ghanbari <i>et al.</i> ⁶² (2016)	Iran	Adolescents aged 15-18 years (mean age=16.2±1.03)	HELMA	582 (48.8)	Multi-stage sampling	High schools
24	Paakkari <i>et al.</i> ⁶³ (2016)	Finland	Pupils (7 th graders aged 13 years: n=1918; 9 th graders aged 15 years: n=1935)	HLSAC	3853 (na)	Cluster sampling	Secondary schools
25	Manganello <i>et al.</i>	USA	Adolescents aged 14-19 years	REALM-TeenS	174 (na)	na	Adolescent medicine

Study no	Author (Year)	Country	Target population	Health literacy instrument	Sample size (% male)	Sampling method	Recruitment setting
26	<i>al.</i> ⁶⁴ (2017) Tsubakita <i>et al.</i> ⁶⁵ (2017)	Japan	(mean age=16.6) Young adults aged 18-26 years (mean age=19.65±1.34)	funHLS-YA	1751 (76.8)	Convenience sampling	clinics A private university
27	Intarakamhang <i>et al.</i> ⁶⁶ (2017)	Thailand	Overweight children aged 9-14 years	HLS-TCO	2000 (na)	Quota-stratified random sampling	Schools
28	Bradley-Klug <i>et al.</i> ⁶⁷ (2017)	USA	Youth and young adults with chronic health conditions aged 13-21 years (mean age=17.6)	HLRS-Y	204 (24.3)	National sampling	Community-based agencies and social media outlets
29	Quemelo <i>et al.</i> ⁶⁸ (2017)	Brazil	University students (mean age=22.7±5.3)	p_HLAT-8	472 (33.9)	na	A university

Note: na, no information available. CHC Test, Critical Health Competence Test; CHLT, Child Health Literacy Test; c-STOFHLAd, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; funHLS-YA, Functional Health Literacy Scale for Young Adults; HAS-A, Health Literacy Assessment Scale for Adolescents; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, 8-item Health Literacy Assessment Tool; HLAT-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; VOHL, Visual Oral Health Literacy.

General characteristics of included instruments

Compared to previous systematic reviews,^{10 11 13} this review identified 19 additional new health literacy instruments (eHEALS, s-TOFHLA, DNT-39, DNT-14, HLAT-51, HLAT-8, CHLT, VOHL, HAS-A, QuALiSMental, FCCHL-AYAC, ICHL, HELMA, HLSAC, REALM-TeenS, funHLS-YA, HLS-TCO, HLRS-Y and p_HLAT-8). The 29 health literacy instruments were classified into three groups based on whether the instrument was developed bespoke for the study or not (See **Table 2**).¹⁰ The three groups were: (1) newly-developed instruments for childhood, adolescent and youth health literacy (n=20),^{40-47 49 50 55-58 61-63 65-67} (2) adapted instruments that were based on previous instruments for adult/adolescent health literacy (n=6),^{51 53 59 60 64 68} and (3) original instruments that were developed for adult health literacy (n=3).^{39 48 50 52}

Health literacy domains and components

Next, Nutbeam's three-domain health literacy model¹⁷ was used to classify the 29 instruments according to which of the commonly-used components of health literacy were included. Results showed that ten instruments measured only functional health literacy^{39 41 48 50-53 56 64 65} and one instrument measured only critical health literacy.⁴⁷ There was one instrument measuring functional and interactive health literacy⁴⁶, one measuring functional and critical health literacy⁴⁰, and one measuring interactive and critical health literacy.⁶¹ Fifteen instruments measured health literacy by all three domains (functional, interactive and critical).^{42-45 49 55 57-60 62 63 66-68}

Consideration of participants' characteristics

As per Forrest *et al.*'s 4D model,^{14 15} the 29 included instruments were examined for whether participant characteristics were considered when developing a new instrument or validating an existing instrument. Results showed most of the health literacy instruments considered developmental change, dependency and demographic patterns. In contrast, only seven instruments considered differential epidemiology.^{53 58}
^{60 61 66 67}

Health topics, contents and readability levels

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3 Health literacy instruments for children and adolescents covered a range of health
4 topics such as nutrition and sexual health. Most instruments (n=26) measured health
5 literacy in healthcare settings or health promotion contexts (e.g. general health topics,
6 oral health, or mental health), while only three instruments measured health literacy in
7 the specific context of eHealth or media health.^{42 43 49} In relation to the readability of
8 tested materials, only eight health literacy instruments reported their readability levels,
9 ranging from 2th to 19.5th grade.
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15 Burden and forms of administration

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18 The time to administer was reported in seven instruments, ranging from 3 to 90
19 minutes. There were three forms of administration: self-administered instruments
20 (n=19), interviewer-administered instruments (n=9), and video-assisted, interviewer-
21 administered instruments (n=1). Regarding the method of assessment, fifteen
22 instruments were performance-based, eleven instruments were self-report, and three
23 included both performance-based and self-report items.
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Table 2. General and important characteristics of included instruments used in children and adolescents

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
1	NVS ^{50,54,39}	Functional HL 1. Reading comprehension (2) 2. Numeracy (4)	Demographic patterns	Nutrition-related information about the label of an ice cream container (na)	Open-ended	Score range: 0-6; Ordinal category: 0-1: high likelihood of limited literacy; 2-3: possibility of limited literacy; 4-6: adequate literacy	No longer than 3 minutes	Interviewer-administered & Performance-based
2	TOFHLA ⁴⁸	Functional HL 1. Reading comprehension (50) 2. Numeracy (17)	Developmental change Demographic patterns	Instruction for preparation for an upper gastrointestinal series (4.3 grade), a standard informed consent form (10.4 grade), patients' rights and responsibilities section of a Medicaid application form (19.5 grade), actual hospital forms & labelled prescription vials (9.4 grade)	4 response options	Score range: 0-100; Ordinal category: 0-59: inadequate health literacy; 60-74: marginal health literacy; 75-100: adequate health literacy	12.9 minutes (8.9-17.3 minutes)	Interviewer-administered & Performance-based
3	s-TOFHLA ⁵⁰	Functional HL 1. Reading comprehension (36)	Demographic patterns	Instruction for preparation for an upper gastrointestinal series (4 th grade), patients' rights and responsibilities section of a Medicaid application form (10 th grade)	4 response options	Score range: 0-36; Ordinal category: 0-16: inadequate literacy; 17-22: marginal literacy; 23-36: adequate literacy	na	Interviewer-administered & Performance-based
4	c-sTOFHLAd ⁵¹	Functional HL 1. Reading comprehension (36)	Developmental change Demographic patterns	Instruction for preparation for an upper gastrointestinal series (4 th grade), patients' rights and responsibilities section of a Medicaid application form (10 th grade)	4 response options	Score range: 0-36; Ordinal category: 0-16: inadequate literacy; 17-22: marginal literacy; 23-36: adequate literacy	20-minute class period	Self-administered & Performance-based
5	REALM-Teen ^{41,50}	Functional HL 1. Reading recognition (66)	Developmental change Demographic patterns	66 health-related words such as weight, prescription and tetanus (6 th grade)	Open-ended	Score range: 0-66; Ordinal category: 0-37: ≤ 3 rd ; 38-47: 4 th -	2-3 minutes	Interviewer-administered & Performance-

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
						5 th ; 48-58: 6 th -7 th ; 59-62: 8 th -9 th ; 63-66: ≥ 10 th		based
6	HLAB ⁴⁰	Functional and critical HL 1. Understanding health information (30) 2. Evaluating health information (17)	Developmental change Demographic patterns	A range of topics such as nutrition and sexual health (pilot-tested)	Open-ended	Score range: 0-107; Continuous score	Two regular classroom sessions	Self-Administered & Performance-based
7	MMAHL ⁴⁴	Functional, interactive and critical HL 1. Patient-provider encounter (4) 2. Interaction with the health care system (5) 3. Rights and responsibilities (7) 4. Confidence in using health information from personal source (3) 5. Confidence in using health information from media source (3) 6. Health information seeking competency using the Internet (2)	Developmental change Demographic patterns Dependency	Experiences of how to access, navigate and manage one's health care and preventive health needs (6 th grade)	5-point Likert scale	Score range: na; Continuous score	na	Self-administered & Self-reported
8	MHL ⁴⁹	Functional, interactive and critical HL 1. Content identification (6) 2. Perceived influence on behaviour (6) 3. Critical analysis and intended (6)	Dependency Demographic patterns	Nutrition/dieting, physical activity, body image, sexual activity, cigarette smoking, alcohol consumption, violent behaviour, safety habits and/or friendship and family connectedness (pilot-tested)	Open-ended & multiple choice	Score range: 0-24; Continuous score	na	Video-assisted interviewer-administered & Performance-based

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
9	DNT-39 ⁵³	4. Action/reaction (6) Functional health literacy 1. Health numeracy (39)	Differential epidemiology Demographic patterns	Nutrition, exercise, blood glucose monitoring and insulin administration (na)	Open-ended	Score range: 0-100; Continuous score	na	Interviewer-administered & Performance-based
10	DNT-14 ⁵³	Functional health literacy 1. Health numeracy (14)	Differential epidemiology Demographic patterns	Nutrition, exercise, blood glucose monitoring and insulin administration (na)	Open-ended	Score range: 0-100; Continuous score	na	Interviewer-administered & Performance-based
11	eHEALS ⁴³	Functional, interactive and critical HL 1. Accessing health information (4) 2. Evaluating health information (2) 3. Applying health information (2)	Developmental change Dependency Demographic patterns	General health topics about online health information (pilot-tested)	5-point Likert scale	Score range: na; Continuous score	na	Self-Administered & Self-reported
12	CHC Test ⁴⁷	Critical HL 1. Understanding medical concepts (15) 2. Searching literature skills (22) 3. Basic statistics (18) 4. Design of experiments and sampling (17)	Developmental change Demographic patterns	Echinacea and common cold, magnetic resonance imaging in knee injuries, treatment of acne, breast cancer screening (pilot-tested)	Open-ended & multiple choice	na	Less than 90 minutes	Interviewer-administered & Performance-based
13	HKACSS ⁴⁶	Functional and interactive HL 1. Health knowledge (3) 2. Health attitudes (4) 3. Health communication (3) 4. Self-efficacy (3)	Developmental change Dependency Demographic patterns	Physical activities, nutrition, smoking, vaccination, tooth health and general health (na)	2 response options; 5-point Likert scale; 4-point Likert	Score range: na; Continuous score	na	Self-Administered & Performance-based & Self-reported

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
14	HLAT-51 ⁴²	Functional, interactive and critical HL 1. Comprehension skill (20) 2. Health numeracy (11) 3. Media literacy (8) 4. Digital literacy (12)	Developmental change Dependency Demographic patterns	Health topics such as gout and uric acid, high cholesterol and triglyceride levels, health-information-seeking skills (na)	scale Yes/no; multiple choice	na	30-45 minutes	Self-administered & Performance-based & Self-reported
15	HLAT-8 ⁴⁵	Functional, interactive and critical HL 1. Understanding health information (2) 2. Finding health information (2) 3. Interactive health literacy (2) 4. Critical health literacy (2)	Dependency Demographic patterns	General health topics in people's daily life (na)	5-point Likert scale; 4- point Likert scale	Score range: 0-37; Continuous score	na	Self-administered & Self-reported
16	CHLT ⁵⁵	Functional, interactive and critical HL 1. Health knowledge (11) 2. Health attitude (16) 3. Health skills (5)	Developmental change Dependency Demographic patterns	Personal hygiene, growth and aging, sexual education and mental health, healthy eating, safety and first aid, medicine safety, substance abuse prevention, health promotion and disease prevention, consumer health, health and environment (pilot-tested)	Multiple choice	Score range: 0-32; Continuous score	na	Self-administered & Performance-based
17	VOHL ⁵⁶	Functional HL 1. Health knowledge (2)	Developmental change	Oral health for tooth & gingiva (na)	Visual drawing	Score range: 0-6; Continuous score	na	Self-administered & Performance-based
18	HAS-A ⁵⁷	Functional, interactive and	Developmental change	General health topics in daily	5-point	Score range: 0-24	na	Self-

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
		critical HL	Demographic patterns	life (pilot-tested)	Likert scale	(understanding), 0-20 (communication), 0-16 (confusion); Continuous score		administered & Self-reported
		1. Understanding health information (6)	Dependency					
		2. Communication health information (5)						
		3. Confusion about health information (4)						
19	MaHeLi ⁵⁸	Functional, interactive and critical HL	Developmental change	General health and maternal health topics (na)	6-point Likert scale	na	na	Interviewer-administered & Self-reported
		1. Health seeking-behaviour (1)	Demographic patterns					
		2. Competence and coping skills (6)	Dependency					
		3. Appraisal of health information (5)	Differential epidemiology					
20	QuALiSMental ⁵⁹	Functional, interactive and critical HL	Developmental change	Mental health vignettes (na)	Yes/no; Multiple choice	na	40-50 minutes	Self-administered & Performance-based
		1. Recognition disorders (14)	Demographic patterns					
		2. Knowledge about the professionals and treatments available (16)	Dependency					
		3. Knowledge of the effectiveness of self-help strategies (12)						
		4. Knowledge and skills needed to provide support and first aid to others (10)						
		5. Knowledge of how to prevent mental disorders (8)						

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
21	FCCHL-AYA ⁶⁰	Functional, interactive and critical HL 1. Functional HL (6) 2. Communicative HL(3) 3. Critical HL (4)	Developmental change Dependency Differential epidemiology	Health topics regarding cancer in daily life (2 nd grade)	4-point Likert scale	Score range: 13-52; Continuous score	na	Self-administered & Self-reported
22	ICHL ⁶¹	Interactive and critical HL 1. Interactive HL (2) 2. Critical HL (7)	Developmental change Demographic patterns Dependency Differential epidemiology	General health topics in daily life (pilot-tested)	5-point Likert scale	na	40-55 minutes (together with other measures)	Self-administered & Self-reported
23	HELMA ⁶²	Functional, interactive and critical HL 1. Access (5) 2. Reading (5) 3. Understanding (10) 4. Appraise (5) 5. Use (4) 6. Communication (8) 7. Self-efficacy (4) 8. Numeracy (3)	Developmental change Dependency	General health topics in daily life (pilot-tested)	5-point Likert scale	Score range: 0-100; Ordinal category: 0-50: inadequate; 50.1-66: problematic; 66.1-84: sufficient; 84.1-100: excellent	15 minutes	Self-administered & Self-reported
24	HLSAC ⁶³	Functional, interactive and critical HL 1. Theoretical knowledge (2) 2. Practical knowledge (2) 3. Individual critical thinking (2) 4. Self-awareness (2) 5. Citizenship (2)	Developmental change Dependency	General health topics in daily life (7 th grade)	4-point Likert scale	na	45 minutes (together with the HBSC survey)	Self-administered & Self-reported
25	REALM-Teens ⁶⁴	Functional HL 1. Reading recognition (10)	Developmental change Demographic patterns	10 health-related words such as diabetes (6 th grade)	Open-ended	Score range: 0-10; Ordinal category: 0-2: ≤ 3 rd ; 3-4: 4 th -5 th ; 5-6: 6 th -7 th ; 7-8: 8 th -	13.6 seconds (range: 7.8-23.0)	Interviewer-administered & Performance-based

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
26	funHLS-YA ⁶⁵	Functional HL 1. Word recognition and comprehension (19)	Developmental change	Diseases and symptoms, nutrition and diet, biology of the human body (na)	Multiple choice	9 th ; 9-10: ≥ 10 th Score range: na; Continuous score	5 minutes	Self-administered & Performance-based
27	HLS-TCO ⁶⁶	Functional, interactive and critical HL 1. Health knowledge and understanding (10) 2. Accessing information and services (5) 3. Communicating skills (6) 4. Managing health conditions (5) 5. Media literacy (5) 6. Making decisions (4)	Developmental change Demographic patterns Dependency Differential epidemiology	Health information for obesity preventive behaviours (pilot-tested)	Multiple choice; Likert scale	Score range: 0-135; Ordinal category: low: <21 for FHL, <33 for IHL, <27 for CHL; fair: 21-27.99 for FHL, 33-43.99 for IHL, 27-35.99 for CHL; high: 28-35 for FHL, 44-54.9 for IHL, 36-45 for CHL	na	Self-administered & Performance-based & Self-reported
28	HLRS-Y ⁶⁷	Functional, interactive and critical HL 1. Knowledge (10) 2. Self-advocacy/support (14) 3. Resiliency (13)	Developmental change Demographic patterns Differential epidemiology	Health information about chronic health conditions (pilot-tested)	4-point Likert scale	Score range: na; Continuous score	15-20 minutes	Self-administered & Self-reported
29	p_HLAT-8 ⁶⁸	Functional, interactive and critical HL 1. Understanding health information (2) 2. Searching health information (2) 3. Communicating health information (2) Appraising health information (2)	Dependency	General health topics in daily life (pilot-tested)	5-point Likert scale; 4-point Likert scale	Score range: 0-37; Continuous score	na	Self-administered & Self-reported

Note: na, no information available. CHC Test, Critical Health Competence Test; CHLT, Child Health Literacy Test; c-sTOFHLAd, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; funHLS-YA, Functional Health Literacy Scale for Young Adults; HAS-A, Health Literacy Assessment Scale for Adolescents; HBSC, Health Behaviour in School-aged Children; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HL, Health Literacy; HLAB, Health Literacy Assessment Booklet; HLAT-8, 8-item Health Literacy Assessment Tool; HLAT-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; VOHL, Visual Oral Health Literacy.

Evaluation of methodological quality of included studies

According to the COSMIN checklist, the methodological quality of each instrument as assessed by each study is presented in **Table 3**. Almost all studies (n=28) examined content validity, 24 studies assessed internal consistency and hypotheses testing, 17 studies examined structural validity, eight studies assessed test-retest/inter-rater reliability, two studies assessed cross-cultural validity and only one study assessed responsiveness.

Evaluation of instruments' measurement properties

After the methodological quality assessment of included studies, measurement properties of each health literacy instrument were examined according to Terwee's quality criteria (See **Appendix 5**).³⁵ The rating results of measurement properties of each instrument are summarised in **Table 4**.

The synthesised evidence for the overall rating of measurement properties

Finally, a synthesis was conducted for the overall rating of measurement properties for each instrument according to '*the best evidence synthesis*' guidelines recommended by the COSMIN checklist developer group.³² This synthesis result was derived from information presented in **Table 3** and **Table 4**. The overall rating of each measurement property for each health literacy instrument is presented in **Table 5**. In summary, most information (62.9%, 146/232) on measurement properties was unknown due to either poor methodological quality of studies or a lack of information on reporting or assessment.

Table 3. Methodological quality of each study for each measurement property according to the COSMIN checklist

Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsive-ness
					Structural validity	Hypotheses testing	Cross-cultural validity	
NVS (Hoffman <i>et al.</i> , 2013) ⁵⁰	Poor	na	na	Poor	na	Fair	na	na
NVS (Driessnack <i>et al.</i> , 2014) ⁵⁴	Poor	na	na	Poor	na	Poor	na	na
NVS (Warsh <i>et al.</i> , 2014) ³⁹	na	na	na	Poor	na	Fair	na	na
TOFHLA (Chisolm and Buchanan, 2007) ⁴⁸	na	na	na	Poor	na	Fair	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013) ⁵⁰	Poor	na	na	Poor	na	Fair	na	na
c-sTOFHLAd (Chang <i>et al.</i> , 2012) ⁵¹	Fair	Fair	na	Good	Fair	Fair	Fair	na
REALM-Teen (Davis <i>et al.</i> , 2006) ⁴¹	Poor	Fair	na	Good	na	Fair	na	na
REALM-Teen (Hoffman <i>et al.</i> , 2013) ⁵⁰	Poor	na	na	Poor	na	Poor	na	na
HLAB (Wu <i>et al.</i> , 2010) ⁴⁰	Fair	Poor	na	Good	na	Fair	na	na
MMAHL (Massey <i>et al.</i> , 2013) ⁴⁴	Good	na	na	Good	Good	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011) ⁴⁹	Poor	na	na	Good	na	Good	na	na
DNT-39 (Mulvaney <i>et al.</i> , 2013) ⁵³	Fair	na	na	Poor	na	Fair	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013) ⁵³	Fair	na	na	Poor	na	Fair	na	na
eHEALS (Norman <i>et al.</i> , 2006) ⁴³	Fair	Fair	na	Good	Fair	Fair	na	na
CHC Test (Steckelberg <i>et al.</i> , 2009) ⁴⁷	na	Poor	na	Good	Poor	na	na	na
HKACSS (Schmidt <i>et al.</i> , 2010) ⁴⁶	Excellent	na	na	Good	na	Good	na	na
HLAT-51 (Harper, 2014) ⁴²	Poor	na	na	Good	Poor	na	na	na
HLAT-8 (Abel <i>et al.</i> , 2014) ⁴⁵	Excellent	na	na	Poor	Excellent	Good	na	na
CHLT (Liu <i>et al.</i> , 2014) ⁵⁵	Fair	na	na	Good	Fair	Fair	na	na
VOHL (Ueno <i>et al.</i> , 2014) ⁵⁶	na	Fair	na	na	na	Fair	na	Fair
HAS-A (Manganello <i>et al.</i> 2015) ⁵⁷	Fair	na	na	Good	Fair	Fair	na	na
MaHeLi (Naigaga <i>et al.</i> 2015) ⁵⁸	Fair	na	na	Poor	Fair	na	na	na
QuALiSMental (de Jesus Loureiro <i>et al.</i> , 2015) ⁵⁹	Fair	na	na	Excellent	Fair	Fair	na	na
FCCHL-AYAC (McDonald <i>et al.</i> , 2016) ⁶⁰	Fair	na	na	Good	Fair	Fair	na	na

Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsive -ness
					Structural validity	Hypotheses testing	Cross-cultural validity	
ICHL (Smith <i>et al.</i> , 2016) ⁶¹	na	na	na	Good	na	Fair	na	na
HELMA (Ghanbari <i>et al.</i> , 2016) ⁶²	Good	Good	na	Good	Good	na	na	na
HLSAC (Paakkari <i>et al.</i> , 2016) ⁶³	Fair	Fair	na	Good	Fair	Fair	na	na
REALM-TeenS (Manganello <i>et al.</i> , 2017) ⁶⁴	Good	na	na	Good	na	Good	na	na
funHLS-YA (Tsubakita <i>et al.</i> , 2017) ⁶⁵	Fair	na	na	Poor	Fair	Fair	na	na
HLS-TCO (Intarakamhang <i>et al.</i> , 2017) ⁶⁶	Fair	na	na	Good	Fair	Fair	na	na
HLRS-Y (Bradley-Klug <i>et al.</i> , 2017) ⁶⁷	Fair	na	na	Excellent	Fair	Fair	na	na
p_HLAT-8 (Quemelo <i>et al.</i> , 2017) ⁶⁸	Fair	na	na	Good	Fair	Fair	Fair	na

Note: na, no information available. CHC Test, Critical Health Competence Test; CHLT, Child Health Literacy Test; c-sTOFHLA, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; funHLS-YA, Functional Health Literacy Scale for Young Adults; HAS-A, Health Literacy Assessment Scale for Adolescents; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, 8-item Health Literacy Assessment Tool; HLAT-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; VOHL, Visual Oral Health Literacy.

Table 4. Evaluation of measurement properties for included instruments according to Terwee's quality criteria

Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsiveness
					Structural validity	Hypotheses testing	Cross-cultural validity	
NVS (Hoffman <i>et al.</i> , 2013) ⁵⁰	-	na	na	?	na	-	na	na
NVS (Driessnack <i>et al.</i> , 2014) ⁵⁴	+	na	na	?	na	-	na	na
NVS (Warsh <i>et al.</i> , 2014) ³⁹	na	na	na	?	na	+	na	na
TOFHLA (Chisolm and Buchanan, 2007) ⁴⁸	na	na	na	?	na	-	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013) ⁵⁰	+	na	na	?	na	-	na	na
c-sTOFHLAd (Chang <i>et al.</i> , 2012) ⁵¹	+	+	na	+	?	+	?	na
REALM-Teen (Davis <i>et al.</i> , 2006) ⁴¹	+	+	na	+	na	+	na	na
REALM-Teen (Hoffman <i>et al.</i> , 2013) ⁵⁰	+	na	na	?	na	-	na	na
HLAB (Wu <i>et al.</i> , 2010) ⁴⁰	+	+	na	+	na	-	na	na
MMAHL (Massey <i>et al.</i> , 2013) ⁴⁴	+	na	na	+	-	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011) ⁴⁹	+	na	na	+	na	+	na	na
DNT-39 (Mulvaney <i>et al.</i> , 2013) ⁵³	+	na	na	?	na	-	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013) ⁵³	+	na	na	?	na	-	na	na
eHEALS (Norman and Skinner, 2006) ⁴³	+	-	na	+	+	-	na	na
CHC Test (Steckelberg <i>et al.</i> , 2009) ⁴⁷	na	+	na	+	+	na	na	na
HKACSS (Schmidt <i>et al.</i> , 2010) ⁴⁶	+(HC) - (HA)	na	na	+	na	+	na	na
HLAT-51 (Harper, 2014) ⁴²	?	na	na	+	?	na	na	na
HLAT-8 (Abel <i>et al.</i> , 2014) ⁴⁵	-	na	na	?	+	+	na	na
CHLT (Liu <i>et al.</i> , 2014) ⁵⁵	+	na	na	+	+	+	na	na
VOHL (Ueno <i>et al.</i> , 2014) ⁵⁶	na	-(TS) + (GS)	na	na	na	-	na	+
HAS-A (Manganello <i>et al.</i> 2015) ⁵⁷	+	na	na	+	+	-	na	na
MaHeLi (Naigaga <i>et al.</i> 2015) ⁵⁸	+	na	na	?	+	na	na	na
QuALiSMental (de Jesus Loureiro <i>et al.</i> , 2015) ⁵⁹	-	na	na	+	+	+	na	na
FCCHL-AYAC (McDonald <i>et al.</i> , 2016) ⁶⁰	+(FHL) - (IHL) +(CHL)	na	na	+	+	-	na	na
ICHL (Smith <i>et al.</i> , 2016) ⁶¹	na	na	na	+	na	+	na	na
HELMA (Ghanbari <i>et al.</i> , 2016) ⁶²	+	+	na	+	+	na	na	na
HLSAC (Paakkari <i>et al.</i> , 2016) ⁶³	+	+	na	+	-	+	na	na
REALM-TeenS (Manganello <i>et al.</i> ,	+	na	na	+	na	+	na	na

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Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsive-ness
					Structural validity	Hypotheses testing	Cross-cultural validity	
2017) ⁶⁴								
funHLS-YA (Tsubakita <i>et al.</i> , 2017) ⁶⁵	+	na	na	?	+	-	na	na
HLS-TCO (Intarakamhang <i>et al.</i> , 2017) ⁶⁶	+	na	na	+	+	+	na	na
HLRS-Y (Bradley-Klug <i>et al.</i> , 2017) ⁶⁷	+	na	na	+	+	+	na	na
p_HLAT-8 (Quemelo <i>et al.</i> , 2017) ⁶⁸	+	na	na	+	+	-	+	na

Note: na, no information available; + positive rating; ? indeterminate rating; - negative rating. CHC Test, Critical Health Competence Test; CHL, Critical Health Literacy; CHLT, Child Health Literacy Test; c-sTOFHLAd, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; FHL, Functional Health Literacy; funHLS-YA, Functional Health Literacy Scale for Young Adults; GS, Gingiva Score; HA, Health Attitude; HAS-A, Health Literacy Assessment Scale for Adolescents; HC, Health Communication; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, 8-item Health Literacy Assessment Tool; HLAT-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; IHL, Interactive Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; TS, Tooth Score; VOHL, Visual Oral Health Literacy.

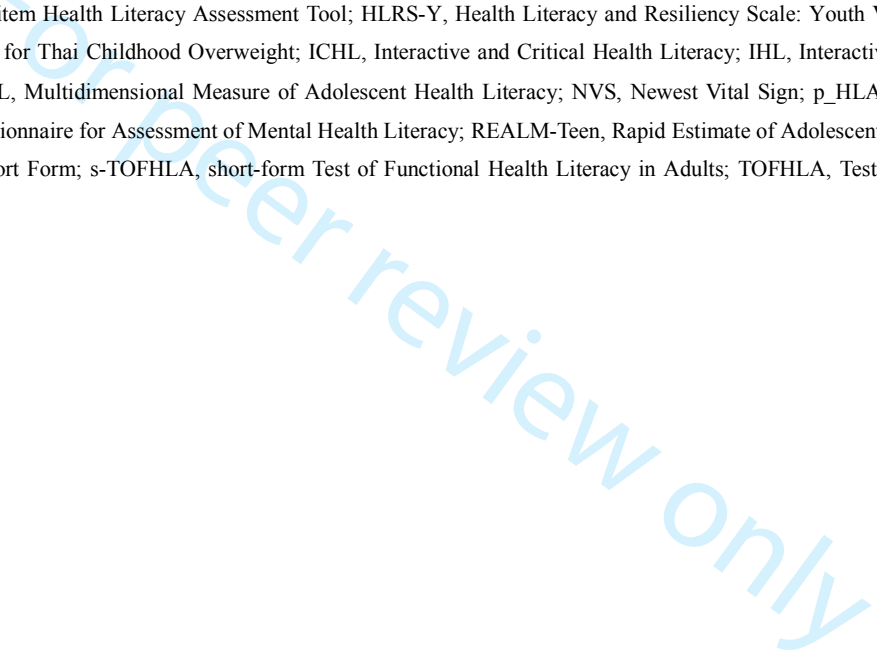
Table 5. The overall quality of measurement properties for each health literacy instrument used in children and adolescents

Health instrument	literacy	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsive-ness
						Structural validity	Hypotheses testing	Cross-cultural validity	
NVS ^{50,54,39}		?	na	na	?	na	±	na	na
TOFHLA ⁴⁸		na	na	na	?	na	-	na	na
s-TOFHLA ⁵⁰		?	na	na	?	na	-	na	na
c-sTOFHLa ⁵¹		+	+	na	++	?	+	?	na
REALM-Teen ^{41,50}		?	+	na	++	na	+	na	na
HLAB ⁴⁰		+	?	na	++	na	-	na	na
MMAHL ⁴⁴		++	na	na	++	--	na	na	na
MHL ⁴⁹		?	na	na	++	na	++	na	na
DNT-39 ⁵³		+	na	na	?	na	-	na	na
DNT-14 ⁵³		+	na	na	?	na	-	na	na
eHEALS ⁴³		+	-	na	++	+	-	na	na
CHC Test ⁴⁷		na	?	na	++	?	na	na	na
HKACSS ⁴⁶		+++ (HC) --- (HA)	na	na	++	na	++	na	na
HLAT-51 ⁴²		?	na	na	++	?	na	na	na
HLAT-8 ⁴⁵		---	na	na	?	+++	++	na	na
CHLT ⁵⁵		+	na	na	++	+	+	na	na
VOHL ⁵⁶		na	- (TS) + (GS)	na	na	na	-	na	+
HAS-A ⁵⁷		+	na	na	++	+	-	na	na
MaHeLi ⁵⁸		+	na	na	?	+	na	na	na
QuALiSMental ⁵⁹		-	na	na	+++	+	+	na	na
FCCHL-AYAC ⁶⁰		+(FHL) -(IHL) +(CHL)	na	na	++	+	-	na	na
ICHL ⁶¹		na	na	na	++	na	+	na	na
HELMA ⁶²		++	++	na	++	++	na	na	na
HLSAC ⁶³		+	+	na	++	-	+	na	na
REALM-TeenS ⁶⁴		++	na	na	++	na	++	na	na
funHLS-YA ⁶⁵		+	na	na	?	+	-	na	na
HLS-TCO ⁶⁶		+	na	na	++	+	+	na	na
HLRS-Y ⁶⁷		+	na	na	+++	+	+	na	na
p_HLAT-8 ⁶⁸		+	na	na	++	+	-	+	na

Note: na, no information available; +++ or --- strong evidence and positive/negative result; ++ or -- moderate evidence and positive/negative result; + or - limited evidence and positive/negative

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result; ± conflicting evidence; ? unknown, due to poor methodological quality or indeterminate rating of a measurement property. CHC Test, Critical Health Competence Test; CHL, Critical Health Literacy; CHLT, Child Health Literacy Test; c-STOFHLAd, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; FHL, Functional Health Literacy; funHLS-YA, Functional Health Literacy Scale for Young Adults; GS, Gingiva Score; HA, Health Attitude; HAS-A, Health Literacy Assessment Scale for Adolescents; HC, Health Communication; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAB-8, 8-item Health Literacy Assessment Tool; HLAB-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; IHL, Interactive Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; TS, Tooth Score; VOHL, Visual Oral Health Literacy.



Discussion

Summary of main results

This study identified and examined 29 health literacy instruments used in children and adolescents and exemplified the large variety of methods used. It showed that to date, only half of included health literacy instruments (15/29) measure all three domains (functional, interactive and critical) and that the functional domain is still the focus of attention when measuring health literacy in children and adolescents. Additionally, researchers mainly focus on participant characteristics of developmental change (of cognitive ability), dependency (on parents) and demographic patterns (e.g. racial/ethnic backgrounds), and less so on differential epidemiology (of health and illness). The methodological quality of included studies as assessed via measurement properties varied from poor to excellent. Most information (62.9%) on measurement properties was unknown due to either the poor methodological quality of studies or a lack of reporting or assessment. It is therefore difficult to draw a robust conclusion about which instrument is the best.

Health literacy measurement in children and adolescents

This review found that health literacy measurement in children and adolescents tends to include Nutbeam's three-domain health literacy construct (i.e. functional, interactive and critical), especially in the past five years. However, almost one third of included instruments focused only on the functional domain (n=10). Unlike health literacy research for patients in clinics, health literacy research for children and adolescents (a comparatively healthy population) should be considered from a health promotion perspective,⁶⁹ rather than a health care or disease management perspective. Integrating interactive and critical domains into health literacy measurement is aligned with the rationale of emphasising empowerment in health promotion for children and adolescents.⁷⁰ The focus of health literacy for this population group should therefore include all three domains and so there is a need for future research to integrate the three domains within health literacy instruments.

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3 Similar to previous findings by Ormshaw *et al.*¹⁰ and Okan *et al.*,¹³ this review also
4 revealed that childhood and adolescent health literacy measurement varied by its
5 dimensions, health topics, forms of administration, and by the level to which
6 participant characteristics were considered. There are likely four main reasons for
7 these disparities. First, definitions of health literacy were inconsistent. Some
8 researchers measured general health literacy,^{40 45} while others measured eHealth
9 literacy or media health literacy.^{43 49} Second, researchers had different research
10 purposes for their studies. Some researchers used what were originally adult
11 instruments to measure adolescent health literacy,^{39 48 52} whereas others developed
12 new or adapted instruments.^{40-42 53} Third, the research settings affected the
13 measurement process. As clinical settings were busy, short surveys were more
14 appropriate than long surveys.^{39 41 44} On the other hand, health literacy in school
15 settings was often measured using long and comprehensive surveys.^{40 42 47} Fourth,
16 researchers considered different participant characteristics when measuring health
17 literacy in children and adolescents. For example, some researchers took
18 considerations of students' cognitive development,^{40 41 44 46 51} some focused on
19 adolescents' resources and environments (e.g. friends and family contexts, eHealth
20 contexts, media contexts),^{43 45 49} and others looked at the effect of different cultural
21 backgrounds and socio-economic status.^{40 41 43 44 46 47 49-52} Based on Forrest *et al.*'s 4D
22 model,^{14 15} this review showed that most health literacy instruments considered
23 participants' development, dependency and demographic patterns, with only seven
24 instruments considering differential epidemiology.^{53 58 60 61 66 67} Although the '4D'
25 model cannot be used to reduce the disparities in health literacy measurement, it does
26 provide an opportunity to identify gaps in current research and assist researchers to
27 consider participants' characteristics comprehensively in future research.
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45 **The methodological quality of included studies**

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48 This review included a methodological quality assessment of included studies, which
49 was absent from previous reviews on this subject.^{10 11} Methodological quality
50 assessment is important because strong conclusions about the measurement properties
51 of instruments can only be drawn from high-quality studies. In this review, the
52 COSMIN checklist was shown to be a useful framework for critically appraising the
53 methodological quality of studies via each measurement property. Findings suggested
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3 that there was wide variation in the methodological quality of studies for all
4 instruments. Poor methodological quality of studies was often seen in the original or
5 adapted health literacy instruments (the NVS, the TOFHLA, the s-TOFHLA, the
6 DNT-39 and the DNT-14) for two main reasons. The first reason was the vague
7 description of the target population involved. This suggested that researchers were
8 less likely to consider an instrument's content validity when using the original, adult
9 instrument for children and/or adolescents. Given that children and adolescents have
10 less well-developed cognitive abilities, in future it is essential to assess whether all
11 items within an instrument are understood. The second reason was a lack of uni-
12 dimensionality analysis for internal consistency. As explained by the COSMIN
13 group,⁷¹ a set of items can be inter-related and multi-dimensional, whereas uni-
14 dimensionality is a prerequisite for a clear interpretation of the internal consistency
15 statistics (Cronbach's alpha). Future research on the use of health literacy instruments
16 therefore needs to assess and report both internal consistency statistics and uni-
17 dimensionality analysis (e.g. factor analysis).
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28 **Critical appraisal of measurement properties for included** 29 **instruments** 30 31 32

33 This review demonstrated that of all instruments reviewed three instruments (the
34 c-TOFHLAd, the HELMA and the HLSAC) showed satisfactory evidence about
35 internal consistency and test-retest reliability. Based on the synthesised evidence, the
36 HELMA showed moderate evidence and positive results of internal consistency
37 ($\alpha=0.93$) and test-retest reliability (intraclass correlation coefficient (ICC)=0.93),
38 whereas the HLSAC ($\alpha=0.93$; standardised stability estimate=0.83) and the c-
39 sTOFHLAd ($\alpha=0.85$; ICC=0.95) showed limited evidence and positive results.
40 Interestingly, compared to the overall reliability rating of the s-TOFHLA,⁵⁰ the c-
41 sTOFHLAd showed better results.⁷² The reason for this was probably the different
42 methodological quality of the studies that examined the s-TOFHLA and the c-
43 sTOFHLAd. The c-sTOFHLAd study had fair methodological quality in terms of
44 internal consistency and test-retest reliability, whereas the original s-TOFHLA study
45 had poor methodological quality for internal consistency and unknown information
46 for test-retest reliability. Given the large disparity of rating results between the
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3 original and translated instrument, further evidence is needed to confirm whether the
4 s-TOFHLA has the same or a different reliability within different cultures, thus
5 assisting researchers to understand the generalisability of the s-TOFHLA's reliability
6 results.
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10 Four instruments were found to show satisfactory evidence about both content
11 validity and construct validity (structural validity and hypotheses testing). Construct
12 validity is a fundamental aspect of psychometrics and was examined in this review for
13 two reasons. First, it enables an instrument to be assessed for the extent to which
14 operational variables adequately represent underlying theoretical constructs.⁷³ Second,
15 the overall rating results of content validity for all included instruments were similar
16 (i.e. unknown or moderate/strong evidence and positive result). The only difference
17 was that the target population was involved or not. Given that all instruments' items
18 reflected the measured construct, in this review, construct validity was determined to
19 be key to examining the overall validity of included instruments. In this context, only
20 the HLAT-8 showed strong evidence and positive result for structural validity
21 (CFI=0.99; TLI=0.97; RMSEA=0.03; SRMR=0.03) and moderate evidence on
22 hypotheses testing (known-group validity results showed differences of health literacy
23 by gender, educational status and health valuation). However, in the original paper,⁴⁵
24 the HLAT-8 was only tested for its known-group validity, not for convergent validity.
25 Examination of convergent validity is important because it assists researchers in
26 understanding the extent to which two examined measures' constructs are
27 theoretically and practically related.⁷⁴ Therefore, future research on the convergent
28 validity of the HLAT-8 would be beneficial for complementing that which exists for
29 its construct validity.
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44 Similar to a previous study by Jordan *et al.*,²⁶ this review demonstrated that only one
45 included study contained evidence of responsiveness. Ueno *et al.*⁵⁶ developed a visual
46 oral health literacy instrument and examined responsiveness by comparing changes in
47 health literacy before and after oral health education. Their results showed students'
48 health literacy scores increased significantly after health education. Responsiveness is
49 the ability of an instrument to detect change over time in the construct being measured,
50 and it is particularly important for longitudinal studies.³¹ However, most studies
51 included in this review were cross-sectional studies, and only one study (on the
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3 MMAHL⁴⁴) discussed the potential to measure health literacy over time. Studies that
4 measure health literacy over time in populations are needed, not only because this is a
5 prerequisite for longitudinal studies, but also so that the responsiveness of instruments
6 can be monitored and improved.
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10 **Feasibility issues for included instruments**

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14 This review showed that the feasibility aspects of instruments varied markedly. In
15 relation to forms of administration, this review identified 19 self-administered
16 instruments and 10 interviewer-administered instruments. This suggests that self-
17 administered instruments are more commonly used in practice than interviewer-
18 administered instruments. However, both administration modes have limitations. Self-
19 administered instruments are cost-effective and efficient, but may bring about
20 respondent bias, whereas interviewer-administered instruments, while able to ensure
21 high response rates, are always resource intensive and expensive to administer.⁷⁵
22 Although the literature showed that there was no significant difference in scores
23 outcome between these two administration modes,^{76 77} the relevant studies mostly
24 concerned health-related quality of life instruments. It is still unknown whether the
25 same is true for health literacy instruments. Among children and adolescents, health
26 literacy research is more likely to be conducted through large-scale surveys in school
27 settings. Therefore, the more cost-effective, self-administered mode seems to have
28 great potential for future research. To further support the wide use of self-
29 administered instruments, there is a need for future research to confirm the same
30 effect of administration between self-administered and interviewer-administered
31 instruments.
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45 With regard to the type of assessment method, this review revealed that performance-
46 based health literacy instruments (n=15) are more preferable than self-report
47 instruments (n=11). There might be two reasons for this. First, it is due to participant
48 characteristics. Compared with adults, children and adolescents are more dependent
49 on their parents for health-related decisions.¹⁵ Measurement error is more likely to
50 occur when children and adolescents answer self-report items.⁷⁸ Therefore,
51 performance-based assessment is often selected to avoid such inaccuracy. Second,
52 performance-based instruments are objective, whereas self-report instruments are
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3 subjective and may bring about over-estimated results.⁷⁹ However, the frequent use of
4 performance-based instruments does not mean that they are more appropriate than
5 self-report instruments when measuring childhood and adolescent health literacy.
6 Compared with performance-based instruments, self-report instruments are always
7 time-efficient and help to preserve respondents' dignity.²¹ The challenge in using self-
8 report instruments is to consider the readability of tested materials. If children and
9 adolescents can understand what a health literacy instrument measures, then they are
10 more able to accurately self-assess their own health literacy skills.⁷⁰ The difference
11 between self-report and performance-based instruments of health literacy has been
12 discussed in the literature,⁸⁰ but the evidence about the difference is still limited due
13 to a lack of specifically-designed studies for exploring the difference. Further studies
14 are needed to fill this knowledge gap.
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24 **Recommendations for future research**

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27 This review identified 18 instruments (the REALM-Teen, the NVS, the s-TOFHLA,
28 the c-sTOFHLAd, the eHEALS, the CHC Test, the HKACSS, the HLAB, the MHL,
29 the HLAT-51, the CHLT, the VOHL, the QuALiSMental, the HELMA, the HLSAC,
30 the funHLS-YA, the HLS-TCO and the p_HLAT-8) that were used to measure health
31 literacy in school settings. Although it is difficult to categorically state which
32 instrument is the best, this review provides useful information that will assist
33 researchers to identify the most suitable instrument to use when measuring health
34 literacy in children and adolescents in school contexts.
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41 Among the 18 instruments, six tested functional health literacy (the REALM-Teen,
42 the NVS, the s-TOFHLA, the c-sTOFHLAd, the VOHL and the funHLS-YA); one
43 examined critical health literacy (the CHC Test); one measured functional and
44 interactive health literacy (the HKACSS); one examined functional and critical health
45 literacy (the HLAB); and nine tested health literacy comprehensively focusing on
46 functional, interactive and critical domains (the eHEALS, the MHL, the HLAT-51,
47 the CHLT, the QuALiSMental, the HELMA, the HLSAC, the HLS-TCO and the
48 p_HLAT-8). However, only one of these three-domain instruments (the HLSAC) was
49 considered appropriate for use in schools because of its quick administration,
50 satisfactory reliability and one-factor validity. Eight three-domain instruments were
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3 excluded due to the fact that they focused on non-general health literacy (the eHEALS,
4 the MHL, the QuALiSMental, the HLS-TCO) or were burdensome to administer (the
5 HLAT-51, the HELMA-44) or were not published in English (the CHLT and the
6 p_HLAT-8).
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11 Compared with the HLSAC, the HLAT-8 examines the construct of health literacy via
12 three domains rather than one-factor structure, thus enabling a more comprehensive
13 examination of the construct. Meanwhile, although the p_HLAT-8 (Portuguese
14 version) is not available in English, the original HLAT-8 is. After comparing
15 measurement domains and measurement properties, the HLAT-8 was deemed to be
16 more suitable for measuring health literacy in school settings for four reasons: (1) it
17 measures health literacy in the context of family and friends,⁴⁵ a highly important
18 attribute because children and adolescents often need support for health decisions
19 from parents and peers;^{7 15} (2) it is a short but comprehensive tool that captures
20 Nutbeam's three-domain nature of health literacy;¹⁷ (3) it showed satisfactory
21 structural validity (RMSEA=0.03; CFI=0.99; TLI=0.97; SRMR=0.03);⁴⁵ and (4) it
22 has good feasibility (e.g. the p_HLAT-8 is self-administered and time-efficient) in
23 school-based studies. However, there are still two main aspects that need to be
24 considered in future. One aspect is its use in the target population. Given the HLAT-8
25 has not been tested for children and adolescents under 18, its readability and
26 measurement properties need to be evaluated. The other aspect is that its convergent
27 validity (the strength of association between two measures of a similar construct, an
28 essential part of construct validity) has not been examined. Testing convergent
29 validity of the HLAT-8 is important because high convergent validity assists
30 researchers to understand the extent to which two examined measures' constructs are
31 theoretically and practically related.
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46 **Limitations**

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49 This review was not without limitation. First, we restricted the search to studies
50 aiming to develop or validate a health literacy instrument. Thus we may have missed
51 relevant instruments in studies that were not aiming to develop instruments.^{81 82}
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53 Second, although the COSMIN checklist provided us with strong evidence of the
54 methodological quality of a study via an assessment of each measurement property, it
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cannot evaluate a study's overall methodological quality. Third, criterion validity was not examined due to lack of 'gold standard' for health literacy measurement. However, we examined convergent validity under the domain of 'hypotheses testing'. This can ascertain the validity of newly-developed instruments against existing commonly-used instruments. Finally, individual subjectivity inevitably played a part in the screening, data extraction and synthesis stage of the review. To reduce this subjectivity, two authors independently managed the major stages.

CONCLUSION

This review updated previous reviews of childhood and adolescent health literacy measurement and incorporated a quality assessment framework. It showed that most information on measurement properties was unknown due to either the poor methodological quality of studies or a lack of assessment and reporting. Rigorous and high-quality studies are needed to fill the knowledge gap in relation to health literacy measurement in children and adolescents. Although it is challenging to draw a robust conclusion about which instrument is the best, this review provides important evidence that supports the use of the HLAT-8 to measure childhood and adolescent health literacy in future research.

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CONTRIBUTORS

SG conceived the review approach. RA and EW provided general guidance for the drafting of the protocol. SG and SA screened the literature. SG and TS extracted data. SG drafted the manuscript. SG, GB, RA, EW, XY, SA and TS reviewed and revised the manuscript.

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None.

DATA SHARING STATEMENT

There are no additional data available.

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For peer review only

FIGURE

Figure 1. Flowchart of search and selection process according to PRISMA flow diagram

For peer review only

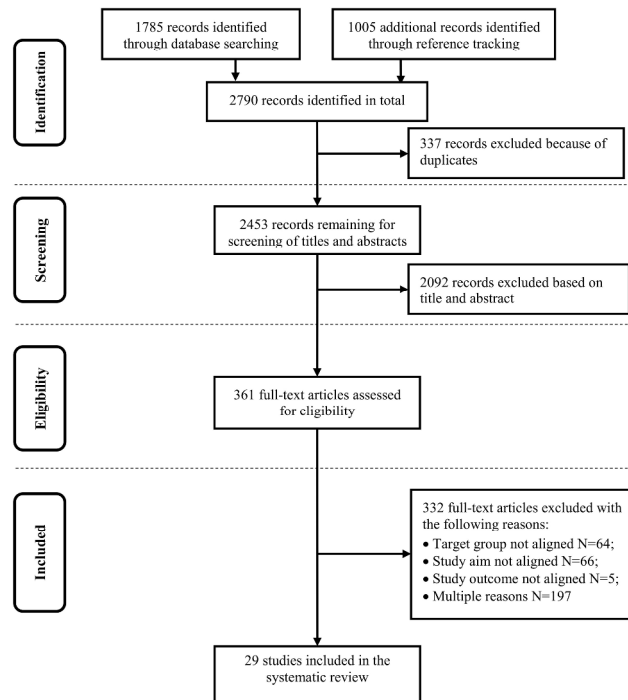


Figure 1. Flowchart of search and selection process according to PRISMA flow diagram

297x420mm (300 x 300 DPI)

Appendix 1. A systematic review protocol

Measuring the Quality of Child and Adolescent Health Literacy Instruments: A Systematic Review

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Background

Health literacy research has been a growing interest by researchers across the globe. The term ‘health literacy’ was first used in 1974 in the proceedings of a health education conference discussing health education as a social policy issue affecting the healthcare system, mass communication and the education system (1, 2). However, few references were found regarding health literacy in the literature until 1992 (3). Since 1992, health literacy has been broadly studied both in clinical and public health contexts. In clinical settings, health literacy is typically defined as ‘the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions’ by the Institute of Medicine (IOM) in America (4). In such circumstances, health literacy is a derivative concept from literacy and numeracy skills, which is often used as a risk factor that needs to be identified and appropriately managed for patients and health professionals (5). Accordingly, health literacy measurement tools and ‘screening aids’ for clinicians are developed to assess patient literacy levels, and help health professionals to tailor health information for better communication with their patients (6). From the public health perspective, health literacy is defined and accepted by World Health Organization (WHO) as ‘the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health’ (7). This understanding of health literacy identifies it as a broad concept, which is seen as a personal asset to enable individuals to take more control over their health and determinants of health (5). With a different understanding of the concept, health literacy measures vary in a different way. Although health literacy measurement varies and is still being debated (1, 8-10), there is

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3 consistent evidence showing health literacy is of potential importance and considered as a
4 public health goal internationally. A recent WHO report pointed out that poor health literacy
5 skills were associated with riskier behaviours, poorer health status, less self-management and
6 longer hospitalization and more health costs (11).
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10 Based on a preliminary search of health literacy, there were more interests in studies focusing
11 on adult health literacy than adolescent health literacy. However, previous research studies
12 suggested that poor health literacy was a prevalent problem in adolescents. In Australia, the
13 2006 National Health Literacy Survey reported that 67.6% of adolescents aged 15 to 19 years
14 old did not attain the minimum skills required to deal with health information and service in
15 everyday life (12). Compared with adult health literacy, there are several reasons for the
16 potential importance of adolescent health literacy: 1) adolescents are future mainstream and
17 independent healthcare consumers, a health literate person can contribute to less health care
18 costs, better health status compared to that is not health literate (13); 2) adolescents are at a
19 critical stage of development characterised by physical, emotional and cognitive changes,
20 attempting to prepare for independence but lacking the adequate ability of reasoning and
21 decision-making. Therefore, improving their health literacy skills could support sound health
22 decisions in future (14, 15); 3) low health literacy has been demonstrated to associate with high
23 levels of health-risk behaviors (16, 17) and low levels of health-promoting behaviors for
24 adolescents (18); 4) enhancing health literacy through school-based interventions has great
25 potential for improving students' access to and interpretation of health information (19).
26 Adolescents spend most of their daily time in school, which means they can receive health
27 education and learn how to improve healthy lifestyles and related skills through this setting (20,
28 21).
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40 Health literacy is more challenging to understand for adolescents than that for adults.
41 Researchers may have different understandings and underlying constructs when using the same
42 definition. That is why there are such a large number of measurement tools of health literacy
43 currently (22, 23), along with some newly-developed health literacy instruments (24).
44 According to Mancuso (1), it is recommended to use specific assessment tools for a specific
45 age group in a specific context. Studies measuring childhood and adolescent health literacy
46 have been a research focus, particularly in the past five years (23). Ormshaw *et al.* (23)
47 conducted a systematic review on measuring childhood and adolescent health literacy in 2011.
48 They found 16 studies that were involved with health literacy measures in children and
49 adolescents. The authors also identified 13 health topics and nine underlying components from
50 existing health literacy instruments. However, the authors did not critically appraise health
51 literacy indices explicitly regarding their validity and reliability. More importantly, the authors
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3 did not assess the methodological quality of each included study. This may undermine the
4 persuasiveness of its conclusion. To fill this knowledge gap, we aim to conduct a systematic
5 review that examines studies' methodological quality and examine reliability and validity of
6 each health literacy instrument, thus providing researchers with unbiased information about
7 which instruments have good psychometric properties. The '*CO*n*SENS*us-based *ST*andards for
8 the selection of health status Measurement *IN*struments' (COSMIN) group has recently
9 developed as a critical appraisal tool (a checklist) to evaluate the methodological quality of
10 studies on measurement properties of health measurement instruments (25). These
11 measurement properties are divided into three domains: reliability, validity, and responsiveness
12 (26). According to the COSMIN checklist, it is possible and scientific to critically appraise and
13 compare psychometric properties of health literacy instruments for children and adolescents.
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21 In this protocol, our target population is adolescent. According to the definition of the WHO,
22 adolescents are those people aged 10 to 19 years and young people aged 10-24 years (27, 28).
23 Given that the term '*adolescent*', '*child*', '*youth*' and '*young people*' is closely related, and
24 Erikson (29) reckoned that children between the ages of 6 and 12 years could learn, compete
25 and co-operate with others, we define our target group as those aged 6-24 years old.
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29 **Objectives of the review**

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32 This review aims to identify which health literacy instruments have good psychometric
33 properties for children and adolescents. Specifically, there are three objectives:

- 34 1) To examine the methodological quality of included studies that aim to measure
35 health literacy in children and adolescents;
- 36 2) To examine the measurement properties (i.e. reliability; validity; responsiveness) of
37 health literacy instruments in children and adolescents;
- 38 3) To compare the overall rating of measurement properties between each health
39 literacy instrument used in children and adolescents.
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46 **Search strategy**

47 ***Database and search terms***

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49 As the term '*health literacy*' was first coined in 1974, articles published from 1st, January 1974
50 to 30th May 2014 in all languages will be searched. Search strategies will be first designed and
51 then be consulted with two librarian experts. Articles indexed in the following seven databases:
52 Medline, Pubmed, Embase, PsycINFO, CINAHL, ERIC and Cochrane Library will be searched.
53 The search key terms are '*health literacy*' and '*assessment*' according to previously published
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studies (1, 23, 30, 31). Age group for ‘child, adolescent and young adult’ will be defined in the database settings. The synonyms are listed in **Appendix Table 1**. These synonyms are connected by ‘or’ and search strategies are completed by ‘and’.

Appendix Table 1 Searching terms in databases

Key term (1)	Key term (2)
health literacy	health literacy measur*
health AND literacy AND education	health literacy assess*
	health literacy evaluat*
	health literacy instrument*
	health literacy tool*

Other sources of literature

Searching other sources to identify relevant research including:

- Reference lists of identified studies;
- Reference lists of previous systematic reviews on health literacy (1, 23, 30-33).

Eligibility criteria for inclusion and exclusion

According to the guidelines recommended by Cochrane Handbook for systematic reviews (34), inclusion criteria will be addressed regarding population, intervention, comparison, outcome and study design (PICOS):

Inclusion criteria-Participants

The target group should be children and/or adolescents, any age from 6 to 24 years of age.

Inclusion criteria-Interventions and Comparators

As interventional studies are not our interest in this review, it is not applicable to set out guidelines for interventions and comparators

Inclusion criteria-Outcomes

The included studies must be involved with health literacy assessment for children and adolescents, that is, the study should specify the term ‘health literacy’, and studies are included if they report on at least one or more attributes of the three measurement properties: 1) reliability; 2) validity; and 3) responsiveness.

Inclusion criteria-Study design

The article should be research-based and peer-reviewed paper including study aim, methods,

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3 and results. Also, the study aim should focus on health literacy instrument development or
4 validation.
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7 ***Exclusion criteria***

8 Studies will be excluded if they are: 1) not focusing on the target group; 2) not focusing on the
9 health literacy instrument development or tool validation; 3) not research-based and peer-
10 reviewed papers including editorials, comments and letters; 4) not reporting findings or results
11 regarding any one of the measurement properties.
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15 **Study selection**

16 Search records will be kept including the names of databases searched, keywords, search
17 timeframe, and the search results. All the electronic search results will be initially inputted into
18 the bibliography software of EndNote X7 (Thomson Reuters, New York, NY), and other
19 sources of literature results will be summarised in the print paper. This screening process will
20 follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)
21 statement (35). One reviewer will screen studies by titles and abstracts. Secondly, full copies of
22 articles identified will be obtained for thorough screening according to the inclusion criteria by
23 two reviewers independently. Any disagreements in reviewer selections will be resolved at a
24 meeting.
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33 **Quality assessment**

34 The methodological quality of each included study will be assessed by two reviewers
35 independently using the COSMIN checklist (25). The checklist consists of nine boxes with 5-
36 18 items concerning methodological standards for how each measurement property should be
37 assessed. Four response options for each item of the COSMIN checklist are defined,
38 representing 'excellent', 'good', 'fair' and 'poor' quality. An overall score for the
39 methodological quality of a study will be determined for each measurement property separately,
40 by taking the lowest rating of any items in a box ('worst score counts') (36). Discrepancies
41 arise between the reviewers will be resolved through discussion, if necessary with a third
42 independent person.
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51 **Data extraction**

52 Data extraction will be performed along with the assessment of methodological quality using
53 the COSMIN checklist (25). In addition, information on the interpretability (e.g. norm scores,
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3 floor-ceiling effects, minimal important change of the instruments), generalisability (e.g.
4 characteristics of the study population and sampling procedure), respondent and administrative
5 burden, and forms of administration will be also collected because they are important
6 characteristics of a measurement instrument (26, 37). The data will be entered in an electronic
7 form. Where possible, authors of the original studies will be contacted to obtain essential
8 missing or additional data. Two reviewers will independently extract the data. Consensus
9 should be reached afterward, if necessary with a third independent person.

14 Data synthesis

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17 The results of the quality of health literacy instruments will be assessed using Terwee's quality
18 criteria (38), to see whether the results of the measurement attributes are '*positive*', '*negative*',
19 or '*indeterminate*'. To summarise the overall ratings of the measurement properties of one
20 health literacy instruments by different authors, the synthesis will be performed by combining
21 the results of the quality of health literacy instruments, the results of methodological quality of
22 health literacy measurement studies and the consistency of their results. The possible overall
23 rating for a measurement property is '*positive*', '*indeterminate*', or '*negative*', accompanied by
24 levels of evidence, similarly as was proposed by the Cochrane Back Review Group (39, 40).
25 One reviewer will perform the data synthesis and a second reviewer will check the synthesised
26 results. Discrepancies of the results will be resolved by discussion.

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Appendix 2. Search strategy for seven databases

This section has two parts for SEARCH STRATEGY. The first part focuses on the timeline of 1974 to 2014. The second part focuses on the timeline of May 2014 to Jan 2018.

Part 1:

1 MEDLINE (Web of Science) search strategy

MEDLINE database was searched using the Web of Science interface on 16/05/2014 for the period 1974 to 2014.

Basic search:

Set	Results	
# 1	500	MeSH HEADING: (health literacy) OR ((TITLE: (health literacy) OR MeSH HEADING:exp: (Health Literacy)) AND (TITLE: (education) OR MeSH HEADING:exp: (Educational Status) OR MeSH HEADINGS:exp: (/education) OR MeSH HEADING:exp: (Teaching) OR MeSH HEADING:exp: (Educational Status) OR MeSH HEADING:exp: (Education))) Refined by: MeSH HEADINGS: (ADOLESCENT OR YOUNG ADULT OR CHILD) Indexes=MEDLINE Timespan=1974-2014
# 2	3,880	TOPIC: (((health) literacy assess* OR health literacy measur*) OR health literacy evaluat*) OR health literacy instrument*) OR health literacy tool*) Indexes=MEDLINE Timespan=1974-2014
# 3	352	#2 AND #1 Indexes=MEDLINE Timespan=1974-2014

2 PubMed search strategy

PubMed database was searched (Advanced search) on 16/05/2014 for the period 1974 to 16/05/2014.

Set	Results	
# 1	4910	Search (health literacy[MeSH Terms]) OR (health AND education AND literacy[Title/Abstract]) Sort by: PublicationDate
# 2	3248385	Search (child* OR adolescent* OR student* OR youth OR young people OR teen* OR young adult[Title/Abstract]) Sort by: PublicationDate Because if we select age group including child, adolescent, and young adult, the newest papers such as published in 2014 will not be included, the reason maybe the database doesn't update properly. So we use these terms to identify.
# 3	1887	Search (health literacy assess* OR health literacy measur* OR health literacy evaluat* OR health literacy instrument* OR health literacy tool*) Sort by: PublicationDate
# 4	581	Search (((health literacy[MeSH Terms]) OR (health AND education AND literacy[Title/Abstract]))) AND ((health literacy assess* OR health literacy measur* OR health literacy evaluat* OR health literacy instrument* OR health literacy tool*)) AND ((child* OR adolescent* OR student* OR youth OR young people OR teen* OR young adult[Title/Abstract])) Filters: Publication date from 1974/01/01 to 2014/05/16 Sort by: PublicationDate

3 EMBASE (Ovid) search strategy

EMBASE database was searched using Ovid interface on 16/05/2014 for the period 1974 to current.

Using .mp as searching terms (Advanced Search):

Set	Results	
#1	<u>6060</u>	("health literacy" or (health and literacy and education)).mp.
#2	<u>6043</u>	limit 1 to yr="1974 -Current"
#3	<u>671</u>	limit 2 to (school child <7 to 12 years> or adolescent <13 to 17 years>)
#4	<u>170</u>	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*).mp.
#5	<u>170</u>	limit 4 to yr="1974 -Current"
#6	<u>18</u>	3 and 5

4 PsycINFO (EBSCO) search strategy

PsycINFO database was searched using EBSCO interface on 16/05/2014 for the period January 1974 to May 2014.

Advanced Search:

Set	Results		
#1	<u>786</u>	health literacy OR (health AND literacy AND education)	Limiters - Published Date: 19740101-20140531; Age Groups: School Age (6-12 yrs), Adolescence (13-17 yrs), Young Adulthood (18-29 yrs) Search modes - Boolean/Phrase
#2	<u>133</u>	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Published Date: 19740101-20140531; Age Groups: School Age (6-12 yrs), Adolescence (13-17 yrs), Young Adulthood (18-29 yrs) Search modes - Boolean/Phrase
#3	<u>133</u>	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*) AND (S1 AND S2)	Search modes - Boolean/Phrase

5 CINAHL (EBSCO) search strategy

CINAHL database was searched using EBSCO interface on 16/05/2014 for the period January 1974 to May 2014.

Advanced Search:

Set	Results		
#1	<u>437</u>	health literacy OR (health AND education AND literacy)	Limiters - Published Date: 19740101-20140531; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase
#2	<u>63</u>	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Published Date: 19740101-20140531; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase
#3	<u>63</u>	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*) AND (S1 AND S2)	Search modes - Boolean/Phrase

6 ERIC (EBSCO) search strategy

ERIC database was searched using EBSCO interface on 16/05/2014 for the period January 1974 to May 2014.

Advanced Search:

Set	Results		
#1	<u>59</u>	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Date Published: 19740101-20140531 Search modes - Boolean/Phrase
#2	<u>2,250</u>	health literacy OR (health AND education AND literacy)	Limiters - Date Published: 19740101-20140531 Search modes - Boolean/Phrase
#3	<u>59</u>	S1 AND S2	Search modes - Boolean/Phrase

7 The Cochrane Library search strategy

The Cochrane Library database was searched on 30/05/2014 for the period January 1974 to May 2014.

Set	Results	Sub-database
#1	<u>4</u>	Cochrane Reviews: There are 4 results from 8483 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords, Publication Date from 1974 to 2014 in Cochrane Reviews'
#2	<u>114</u>	Trials: There are 114 results from 789657 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords, Publication Date from 1974 to 2014 in Trials'
#3	<u>2</u>	Methods Studies: There are 2 results from 15764 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords, Publication Date from 1974 to 2014 in Methods Studies'
#4	<u>120</u>	

Part 2:

The above seven databases were searched using similar rationale as describe before for the timeframe of May 17 2014 to Jan 31 2018.

MEDLINE was searched using the Web of Science interface on 17/02/2018 for the period 2014 to 2018.

Basic search:

Set	Results	
# 5	<u>35</u>	#4 AND #3 Indexes=MEDLINE Timespan=2014-2018
# 4	<u>14,198</u>	MeSH MAJOR TOPIC:exp: ((((((child*) OR adolescent*) OR student*) OR youth) OR young people) OR teen*) OR young adult) Indexes=MEDLINE Timespan=2014-2018

- 1
2
3 # 3 [1,779](#) #2 AND #1
4 Indexes=MEDLINE Timespan=2014-2018
- 5 # 2 [3,482](#) (((TOPIC: (health literacy assess*) OR TOPIC: (health literacy
6 measur*) OR TOPIC: (health literacy instrument*) OR TOPIC: (health literacy
7 tool*) OR TOPIC: (health literacy evaluat*))
8 Indexes=MEDLINE Timespan=2014-2018
- 9 # 1 [2,654](#) ((MeSH HEADING:exp: (health literacy) OR MeSH MAJOR TOPIC:exp: (health
10 literacy)) OR TITLE: (health literacy)) OR MeSH MAJOR TOPIC: ((health) AND
11 education) AND literacy)
12 Indexes=MEDLINE Timespan=2014-2018

13
14
15 **Pubmed** was searched (Advanced search) on 17/02/2018 for the period 2014 to
16 31/01/2018.

17
18
19 **Set Results**

- 20
21
22 #6 [26](#) Search (((((((health literacy[MeSH Terms]) OR health literacy[Title/Abstract]) OR
23 (health[Title/Abstract] AND education[Title/Abstract] AND
24 literacy[Title/Abstract])) OR (health[Title/Abstract] AND
25 education[Title/Abstract] AND numeracy[Title/Abstract]))) AND ((health literacy
26 assess*[Title/Abstract] OR health literacy measur*[Title/Abstract] OR health
27 literacy evaluat*[Title/Abstract] OR health literacy instrument*[Title/Abstract] OR
28 health literacy tool*[Title/Abstract]))) AND ((child*[Title/Abstract] OR
29 adolescent*[Title/Abstract] OR student*[Title/Abstract] OR youth[Title/Abstract]
30 OR young people[Title/Abstract] OR teen*[Title/Abstract] OR young
31 adult[Title/Abstract])) Filters:Publication date from 2014/05/16 to 2018/01/31
- 32 #5 [48](#) Search (((((((health literacy[MeSH Terms]) OR health literacy[Title/Abstract]) OR
33 (health[Title/Abstract] AND education[Title/Abstract] AND
34 literacy[Title/Abstract])) OR (health[Title/Abstract] AND
35 education[Title/Abstract] AND numeracy[Title/Abstract]))) AND ((health literacy
36 assess*[Title/Abstract] OR health literacy measur*[Title/Abstract] OR health
37 literacy evaluat*[Title/Abstract] OR health literacy instrument*[Title/Abstract] OR
38 health literacy tool*[Title/Abstract]))) AND ((child*[Title/Abstract] OR
39 adolescent*[Title/Abstract] OR student*[Title/Abstract] OR youth[Title/Abstract]
40 OR young people[Title/Abstract] OR teen*[Title/Abstract] OR young
41 adult[Title/Abstract]))
- 42 #4 [288](#) Search (((((((health literacy[MeSH Terms]) OR health literacy[Title/Abstract]) OR
43 (health[Title/Abstract] AND education[Title/Abstract] AND
44 literacy[Title/Abstract])) OR (health[Title/Abstract] AND
45 education[Title/Abstract] AND numeracy[Title/Abstract]))) AND ((health literacy
46 assess*[Title/Abstract] OR health literacy measur*[Title/Abstract] OR health
47 literacy evaluat*[Title/Abstract] OR health literacy instrument*[Title/Abstract] OR
48 health literacy tool*[Title/Abstract]))
- 49 #3 [288](#) Search (health literacy assess*[Title/Abstract] OR health literacy
50 measur*[Title/Abstract] OR health literacy evaluat*[Title/Abstract] OR health
51 literacy instrument*[Title/Abstract] OR health literacy tool*[Title/Abstract])
- 52 #2 [1636528](#) Search (child*[Title/Abstract] OR adolescent*[Title/Abstract] OR
53 student*[Title/Abstract] OR youth[Title/Abstract] OR young
54 people[Title/Abstract] OR teen*[Title/Abstract] OR young adult[Title/Abstract])
- 55 #1 [8495](#) Search (((health literacy[MeSH Terms]) OR health literacy[Title/Abstract]) OR
56 (health[Title/Abstract] AND education[Title/Abstract] AND
57 literacy[Title/Abstract])) OR (health[Title/Abstract] AND
58 education[Title/Abstract] AND numeracy[Title/Abstract])

1
2
3 **EMBASE** was searched using Ovid interface on 17/02/2018 for the period 2014 to
4
5 current.

6
7 Using **.mp** as searching terms (Basic Search):

8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
Set	Results																				
#1	11966																				
#2	5862																				
#3	639																				
#4	372																				
#5	26																				

30 **PsycINFO** was searched using Ovid interface on 17/02/2018 for the period May 2014
31
32 to Jan 2018.

33
34
35 Basic Search:

36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57
Set	Results																				
#1	4331																				
#2	<u>2077</u>																				
#3	754																				
#4	216																				
#5	40																				

CINAHL was searched using EBSCO interface on 17/02/2018 for the period May 2014 to Jan 2018.

Basic Search:

Set Results

S1	health literacy OR ((health AND education AND literacy))	Limiters - Published Date: 20140501-20180131; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase	View Results (467)
S2	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Published Date: 20140501-20180131; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase	View Results (118)
S3	S1 AND S2	Search modes - Boolean/Phrase	View Results (118)

ERIC was searched using EBSCO interface on 17/02/2018 for the period May 2014 to Jan 2018.

Basic Search:

Set Results

S1	health literacy OR ((health AND education AND literacy))	Limiters - Date Published: 20140501-20180131 Search modes - Boolean/Phrase	View Results (292)
S2	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Date Published: 20140501-20180131 Search modes - Boolean/Phrase	View Results (13)
S3	(S1 AND S2)	Search modes - Boolean/Phrase	View Results (13)

Cochrane Library was searched on 17/02/2018 for the period May 2014 to Jan 2018.

Set	Results	Sub-database
#1	<u>2</u>	Cochrane Reviews: There are 2 results from 10210 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Year from 2014 to 2018 in Cochrane Reviews'
#2	<u>199</u>	Trials: There are 199 results from 1121096 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Year from 2014 to 2018 in Trials'
#3	201	

Peer review only

Appendix 3. Quality criteria for measurement properties of health literacy instruments

Property	Rating	Quality criteria	
Reliability			
Internal consistency	+	(Sub)scale unidimensional AND Cronbach's alpha(s) ≥ 0.70	
	?	Dimensionality not known OR Cronbach's alpha not determined	
	-	(Sub)scale not unidimensional OR Cronbach's alpha(s) < 0.70	
Measurement error	+	MIC $>$ SDC OR MIC outside the LOA	
	?	MIC not defined	
Reliability	-	MIC \leq SDC OR MIC equals or inside LOA	
	+	ICC/weighted Kappa ≥ 0.70 OR Pearson's $r \geq 0.80$	
	?	Neither ICC/weighted Kappa nor Pearson's r determined	
	-	ICC/weighted Kappa < 0.70 OR Pearson's $r < 0.80$	
Validity			
Content validity	+	The target population considers all items in the questionnaire to be relevant AND considers the questionnaire to be complete	
	?	No target population involvement	
	-	The target population considers items in the questionnaire to be irrelevant OR considers the questionnaire to be incomplete	
Construct validity			
	Structural validity	+	Factors should explain at least 50% of the variance
		?	Explained variance not mentioned
	-	Factors explain $< 50\%$ of the variance	
Hypotheses testing	+	(Correlation with an instrument measuring the same construct ≥ 0.50 OR at least 75% of the results are in accordance with the hypotheses) AND correlation with related constructs is higher than with unrelated constructs	
	?	Solely correlations determined with unrelated constructs	
	-	Correlation with an instrument measuring the same construct < 0.50 OR $< 75\%$ of the results are in accordance with the hypotheses OR correlation with related constructs is lower than with unrelated constructs	
Responsiveness			
Responsiveness	+	(Correlation with an instrument measuring the same construct ≥ 0.50 OR at least 75% of the results are in accordance with the hypotheses OR AUC ≥ 0.70) AND correlation with related constructs is higher than with unrelated constructs	
	?	Solely correlations determined with unrelated constructs	
	-	Correlation with an instrument measuring the same construct < 0.50 OR $< 75\%$ of the results are in accordance with the hypotheses OR AUC < 0.70 OR correlation with related constructs is lower than with unrelated constructs	

Note: AUC, Area Under the Curve; ICC, Intra-class Correlation Coefficient; LOA, Limits of Agreement; MIC, Minimal Important Change; SDC, Smallest Detectable Change. + positive rating; ? indeterminate rating; - negative rating.

Appendix 4. Levels of evidence for the overall rating of measurement properties

Level	Rating	Criteria
Strong	+++ or ---	Consistent findings in multiple studies of good methodological quality OR in one study of excellent methodological quality
Moderate	++ or --	Consistent findings in multiple studies of fair methodological quality OR in one study of good methodological quality
Limited	+ or -	One study of fair methodological quality
Conflicting	±	Conflicting findings
Unknown	?	Only studies of poor methodological quality

Note: + positive result; - negative result; ±conflicting result; ? unknown result.

Appendix 5. Reliability and validity results for included instruments

Appendix Table 1. The methodological quality of each study based on reliability for each health literacy instrument

Instrument	Internal consistency		Reliability			
	Result	COSMIN score	Result	Design	Time interval	COSMIN score
NVS (Warsh <i>et al.</i> , 2014)	na	na	na	na	na	na
NVS (Driessnack <i>et al.</i> , 2014)	$\alpha=0.71$ (n=47)	Poor	na	na	na	na
NVS (Hoffman <i>et al.</i> , 2013)	$\alpha=0.67$ (n=229)	Poor	na	na	na	na
c-sTOFHLAd (Chang <i>et al.</i> , 2012)	$\alpha=0.85$ (n=300) Item-total correlation=0.44-0.86	Fair	Correlation of test and retest was 0.95 ($P<0.001$)	Test-retest	1 week	Fair
TOFHLA (Chisolm and Buchanan, 2007)	na	na	na	na	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013)	$\alpha=0.89$ (n=229)	Poor	na	na	na	na
REALM-Teen (Davis <i>et al.</i> , 2006)	$\alpha=0.94$ (n=388)	Poor	$\gamma=0.98$	Test-retest	1 week	Fair
REALM-Teen (Hoffman <i>et al.</i> , 2013)	$\alpha=0.92$ (n=229)	Poor	na	na	na	na
HLAB (Wu <i>et al.</i> , 2010)	$\alpha=0.92$ (n=275) Understanding $\alpha=0.88$ (n=275) Evaluating $\alpha=0.82$ (n=275)	Fair	Concordance rate=95%	Inter-rater	na	Poor
MMAHL(Massey <i>et al.</i> , 2013)	$\alpha=0.83$ (n=1208) Item-total correlation=0.39-0.74	Good	na	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011)	$\alpha=0.74$ (n=1316) Coefficient of reproducibility=0.84 Coefficients of scalability=0.54-0.80	Poor	na	na	na	na
DNT-39 (Mulvaney <i>et al.</i> , 2013)	$\alpha=0.93$ (n=61)	Fair	na	na	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013)	$\alpha=0.82$ (n=133)	Fair	na	na	na	na

Instrument	Internal consistency		Reliability			
	Result	COSMIN score	Result	Design	Time interval	COSMIN score
	$\alpha=0.80$ (n=61) $\alpha=0.83$ (n=72)					
eHEALS (Norman and Skinner, 2006)	$\alpha=0.88$ (n=664) Item-scale correlation coefficient=0.51-0.76	Fair	The correlations between administrations ranged 0.68-0.40.	Test-retest	Immediately after the intervention; 3-month; 6-month	Fair
CHC Test (Steckelberg <i>et al.</i> , 2009)	na	na	Cohen's Kappa was excellent for 277 ratings ($\kappa=0.9-1.0$), moderate or good for 31 ratings ($\kappa=0.7-0.89$) and poor for 5 ratings ($\kappa<0.7$)	Inter-rater	na	Poor
HKACSS (Schmidt <i>et al.</i> , 2010)	Health knowledge $\chi^2=6.45$, $P=0.17$ (n=852) Health communication $\alpha=0.73$ (n=852) Health attitudes $\alpha=0.57$ (n=852)	Excellent	na	na	na	na
HLAT-51 (Harper, 2014)	Goodness of fit statistic was calculated by each domain (CFI=0.33-0.88; TLI=0.66-0.84; RMSEA=0.09-0.17). The internal consistency statistic was not calculated.	Poor	na	na	na	na
HLAT-8 (Abel <i>et al.</i> , 2014)	$\alpha=0.64$ (n=7097 for male) $\alpha=0.65$ (n=331 for female)	Excellent	na	na	na	na
CHLT (Liu <i>et al.</i> , 2014)	$\alpha=0.87$ (the entire scale); subscales α ranged 0.59 to 0.81	Fair	na	na	na	na
VOHL (Ueno <i>et al.</i> , 2014)	na	na	The kappa value of scoring among the dentists ranged from 0.60 tooth score to 0.70 for gingiva score.	Inter-rater	na	Fair
HAS-A (Manganello <i>et al.</i> , 2015)	$\alpha=0.77$ (communication) $\alpha=0.73$ (confusion) $\alpha=0.76$ (understanding)	Fair	na	na	na	na
MaHeLi (Naigaga <i>et al.</i> 2015)	The person separation index for the original 20-item scale	Fair	na	na	na	na

Instrument	Internal consistency		Reliability			
	Result	COSMIN score	Result	Design	Time interval	COSMIN score
	was 0.91 and $\alpha=0.92$. After item reduction, the person separation index for 12-item scale was 0.90.					
QuALiSMental (de Jesus Loureiro <i>et al.</i> , 2015)	$\alpha=0.55-0.72$ (component 2 and 3) $\alpha=0.44-0.59$ (component 4) $\alpha=0.60-0.82$ (component 5)	Fair	na	na	na	na
FCCHL-AYAC (McDonald <i>et al.</i> , 2016)	$\alpha=0.73$ (FHL) $\alpha=0.63$ (IHL) $\alpha=0.85$ (CHL)	Fair	na	na	na	na
ICHL (Smith <i>et al.</i> , 2016)	na	na	na	na	na	na
HELMA (Ghanbari <i>et al.</i> , 2016)	$\alpha=0.93$ (the entire scale); subscales α ranged 0.61 to 0.89	Good	The intraclass correlation coefficient was 0.93.	Test-retest	Two weeks	Good
HLSAC (Paakkari <i>et al.</i> , 2016)	$\alpha=0.93$ (the entire scale); subscales α ranged 0.69 to 0.77	Fair	The standardised stability estimate was 0.83.	Test-retest	Two weeks	Fair
REALM-TeenS (Manganello <i>et al.</i> , 2017)	$\alpha=0.82$	Good	na	na	na	na
funHLS-YA (Tsubakita <i>et al.</i> , 2017)	$\alpha=0.75$	Fair	na	na	na	na
HLS-TCO (Intarakamhang <i>et al.</i> , 2017)	$\alpha=0.70-0.82$ for five subscales; KR-20=0.76 for health knowledge scale	Fair	na	na	na	na
HLRS-Y (Bradley-Klug <i>et al.</i> , 2017)	$\alpha=0.88$ (Knowledge) $\alpha=0.94$ (Self-advocacy/support) $\alpha=0.93$ (Resiliency)	Fair	na	na	na	na
p_HLAT-8 (Quemelo <i>et al.</i> , 2017)	$\alpha=0.74$ (the entire scale), subscales α ranged 0.41 to 0.71	Fair	na	na	na	na

Note: na, no information available. CFI, Comparative Fit Index; CHC Test, the Critical Health Competence Test; CHL, Critical Health Literacy; CHLT, Child Health Literacy Test; c-sTOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; FCCHL-

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6 AYAC, the Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; FHL, Functional Health Literacy; funHLS-YA, Functional Health Literacy
7 Scale for Young Adults; HAS-A, the Health Literacy Assessment Scale for Adolescents; HELMA, the Health Literacy Measure for Adolescents; HKACSS, the Health Knowledge,
8 Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health
9 Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, The Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale
10 for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; IHL, Interactive Health Literacy; MaHeLi, the Maternal Health Literacy; MHL, the Media Health
11 Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment
12 Tool; QuALiSMental, the Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, the Rapid
13 Estimate of Adolescent Literacy in Medicine Short Form; RMSEA, Root Mean Square Error of Approximation; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults;
14 TLI, Tucker-Lewis Index; TOFHLA, the Test of Functional Health Literacy in Adults; VOHL, the Visual Oral Health Literacy.
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Appendix Table 2. The methodological quality of each study based on validity for each health literacy instrument

Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
NVS (Warsh <i>et al.</i> , 2014)	A panel of health literacy experts developed the NVS according to previous experience. The NVS was then refined after feedback from patients, interviewers, and data analysts. No target population is involved in item generation.	Poor	na	na	Hypotheses regarding correlation between scores of a comparator instrument of Gray Silent Reading Test (GSRT) and NVS were formulated before data collection. The NVS and GSRT scores were highly correlated ($\rho=0.71$, $p<0.0001$). The NVS score increased with child age ($\rho=0.53$, $p<0.0001$).	Fair	na	na
NVS (Driessnack <i>et al.</i> , 2014)	A panel of health literacy experts developed the NVS according to previous experience. The NVS was then refined after feedback from patients, interviewers, and data analysts. No target population is involved in item generation.	Poor	na	na	A moderate positive correlation was found between children's NVS scores and their age, and between children's NVS scores and their reports of books numbers ($\gamma_s=0.43$, $p=0.003$; $\gamma_s=0.36$, $p=0.012$, respectively), but not found with their parents' report of the number of children's books at home ($\gamma_s=0.06$, $p=0.671$).	Poor	na	na
NVS (Hoffman <i>et al.</i> , 2013)	A panel of health literacy experts developed the NVS according to previous experience. The NVS was then refined after feedback from patients, interviewers, and data analysts. No target population is involved in item generation.	Poor	na	na	Convergent validity was measured between NVS and the TerraNova academic achievement test, with a correlation coefficient of 0.49 ($p<0.01$).	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
c-sTOFHLAd (Chang <i>et al.</i> , 2012)	The c-sTOFHLAd was translated from the short-version of TOFHLA according to translation procedures and was tested among 30 adolescents to ensure appropriateness.	Good	Confirmatory factor analysis was conducted to determine structural validity. One-factor model indicated an acceptable fit to the data according structural equation modelling analysis.	Fair	Convergent validity was measured between c-sTOFHLAd and the rapid estimate of adult literacy in medicine (REALM), with a correlation coefficient of 0.74 ($p<0.001$).	Fair	Semantic equivalence was measured by the content validity index (CVI). All items were rated by the experts as having a CVI>0.85. Thirty adolescents were chosen to determine and ensure the cultural congruence of the instrument.	Fair
TOFHLA (Chisolm and Buchanan, 2007)	The TOFHLA was developed from a literacy expert after reviewing commonly used hospital texts and a pilot test. No target population is involved in item generation.	Poor	na	na	The reading comprehension component was significantly correlated with the WRAT3 and the REALM ($\rho=0.59$, $p<0.001$; $\rho=0.60$, $p<0.001$ respectively), however, no correlation were found with the numeracy component ($\rho=0.11$, $p=0.45$; $\rho=0.18$, $p=0.22$ respectively).	Fair	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013)	The s-TOFHLA was developed based on previous data analysis, perceived importance and frequency of the task in the healthcare settings.	Poor	na	na	Convergent validity was measured between NVS and the TerraNova academic achievement test, with a correlation coefficient of 0.28 ($p<0.01$).	Fair	na	na
REALM-Teen (Davis <i>et al.</i> , 2006)	The REALM-Teen was developed based on a preliminary test and a structured interview among adolescents. And a panel of experts reviewed the word	Good	na	na	Convergent validity was measured between REALM-Teen and the WRAT-3 ($r=0.83$) and SORT-R ($r=0.93$).	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
REALM-Teen (Hoffman <i>et al.</i> , 2013)	The REALM-Teen was developed based on a preliminary test and structured interview among adolescents. And a panel of experts reviewed the word list.	Poor	na	na	Convergent validity was measured between NVS and the TerraNova academic achievement test, with a correlation coefficient of 0.40 ($p<0.01$).	Poor	na	na
HLAB (Wu <i>et al.</i> , 2010)	Previous experience and literature review were used to develop items; 10 students were pilot-tested for appropriateness of wording, content and format of the final instrument.	Good	na	na	Correlations were assumed between socio-demographic variables and the overall scores. Socio-demographics of gender, age when came to Canada to live, speaking a language other than English were correlated with the scores of HLAB ($\beta=-0.18$, $p=0.004$; $\beta=-0.22$, $p=0.014$; $\beta=-0.20$, $p=0.008$ respectively). No convergent validity is assessed.	Fair	na	na
MMAHL (Massey <i>et al.</i> , 2013)	Domains were established from literature review and focus group. Items were developed either using adaptation of existing relevant items or created by the research team.	Good	Explorative principal components factor analysis was conducted and 49.8% of the variance was accounted by 6 factors.	Good	na	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011)	The face validity was discussed in the focus group during pilot test. The content validity was analysed using theory and operational definitions of	Good	na	na	As hypothesised, MHL was associated with socio-economic determinants, particularly with gender ($\beta=1.25$, $p<0.001$) and mother's education ($\beta=0.16$, $p=0.04$). In addition, MHL was	Good	na	na

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Instrument	Content validity.....		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
	health literacy and media literacy, and adolescents were invited to write detailed, anonymous responses.				also associated with health behaviours ($\beta=0.03, p=0.05$) and health empowerment ($\beta=0.36, p<0.001$).			
DNT-39 (Mulvaney <i>et al.</i> , 2013)	The DNT-39 was developed from the original 43-item version DNT-43 by eliminating questions specific to type 2 diabetes. An expert team developed the DNT-43 and refined it.	Poor	na	na	The DNT-39 was associated with WRAT-3 and parent education ($\rho=0.40, p=0.001; \rho=0.29, p=0.028$ respectively)	Fair	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013)	The DNT-14 was developed from the original 15-item version DNT-15 by eliminating 1 question specific to type 2 diabetes. An expert team developed the DNT-15 by data analysis from DNT-43.	Poor	na	na	The DNT-14 was associated with the Wide-Ranging Achievement Test (WRAT3), parent education, diabetes problem solving and HbA1c ($\rho=0.36, p=0.005; \rho=0.31, p=0.019; \rho=0.27, p=0.023; \rho=-0.34, p=0.004$ respectively)	Fair	na	na
eHEALS (Norman and Skinner, 2006)	The eHEALS was developed by the expert team and pilot-tested and refined by feedback from participants.	Good	Explorative principal components factor analysis was conducted and 56% of the variance was accounted by a single factor. The factor loadings ranged from 0.60-0.84 among the 8 items.	Fair	Correlations were assumed between eHEALS and other measured variables (gender, age, use of information technology overall, self-evaluations of health). However, only gender difference was found at baseline level of eHealth literacy ($t=2.236, p=0.026$). No convergent validity is assessed.	Fair	na	na
CHC Test (Steckelberg)	The CHC Test was developed by the research	Good	IRT test for determining	Poor	na	na	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
<i>et al.</i> , 2009)	team and pre-tested by collecting qualitative data and quantitative field test.		dimensionality was performed.					
HKACSS (Schmidt <i>et al.</i> , 2010)	The HKACSS items were taken from a previous health survey and selected basing on consideration of item content.	Good	na	na	As hypothesised, health communication, attitudes and self-efficacy were significantly related to each other ($\rho=0.15-0.38$, $P<0.05$). And children from higher educational background showed a better knowledge and communicated more about health topics ($\beta=0.16$, $p<0.05$).	Good	na	na
HLAT-51 (Harper, 2014)	The expert team evaluated the initial items using a 5-point Likert scale according to their research experience. And 144 college students were invited to complete a pilot test.	Good	Comprehension (CFI=0.80; TLI=0.78; RMSEA=0.09); health numeracy (CFI=0.57; TLI=0.48; RMSEA=0.09); media literacy (CFI=0.88; TLI=0.84; RMSEA=0.07); digital literacy (CFI=0.33; TLI=0.06; RMSEA=0.16); health information seeking (CFI=0.80; TLI=0.66; RMSEA=0.17)	Poor	na	na	na	na
HLAT-8 (Abel <i>et al.</i> , 2014)	The research team developed the HALT-8 drawing on literature review and their own	Poor	Explorative principal components factor analysis was conducted and 72.96% of the	Excellent	Hypotheses were formulated a priori regarding correlations between health literacy and gender, socio-cultural	Good	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
	experience. No target population is involved in item generation.		variance was accounted by four factors among male. In addition, the factor structure was validated using confirmatory factor analysis (CFI=0.99; TLI=0.97; RMSEA=0.03; SRMR=0.03).		characteristics and health values. Results showed that female, higher educational status, and a stronger health valuation were associated with higher HL scores ($p<0.05$, respectively).			
CHLT (Liu <i>et al.</i> , 2014)	The research team developed the CHLT drawing on literature review, expert consultation and pilot test. 12 six graders were piloted about the instrument's readability.	Good	Confirmatory factor analysis was conducted to test the uni-dimensionality of each subscale. The factor loadings ranged from 0.20-0.58.	Fair	Hypotheses were formulated a priori regarding correlations between health literacy and gender, self-reported health and health behaviours. Results showed that female, better health status, normal BMI and healthy behaviours were positively associated with HL scores ($p<0.05$, respectively). Health-risky behaviours were negatively associated with health literacy scores ($p<0.05$).	Fair	na	na
VOHL (Ueno <i>et al.</i> , 2014)	na	na	na	na	Correlations were conducted between health literacy and gender. Results showed female students had higher gingiva scores than male students ($p<0.05$). However, no gender differences were found regarding tooth scores.	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
HAS-A (Manganello <i>et al.</i> , 2015)	The research team developed the HAS-A drawing on literature review, expert consultation and pilot test. Scale items were piloted with undergraduates.	Good	Exploratory factor analysis was conducted and 41% of the variance was accounted by three factors.	Fair	Communication scale, confusion scale, and understanding scale were all correlated with the AURA scale ($r=0.69, p<0.001$; $r=-0.50, p<0.001$; $r=-0.42, p<0.001$). The correlation between communication scale, confusion scale and understanding scale and REALM-Teen and NVS were small, ranging from -0.26 to 0.08. Also health literacy scores were compared by demographics. There was no difference in scores by sex or age, but a significant difference by race/ethnicity ($p<0.001$).	Fair	na	na
MaHeLi (Naigaga <i>et al.</i> 2015)	The research team developed the MaHeLi based on the health belief model and integrated model of health literacy. No target population is involved in item generation.	Poor	The health-seeking behaviour (HSB) subscale brought substantial multidimensionality into the MeHeLi scale. After removing most items of the HSB subscale, the MeHeLi scale showed a unidimensionality construct with some but not too noticeable multi-dimensionality.	Fair	na	na	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
QuALiSMental (de Jesus Loureiro <i>et al.</i> , 2015)	The questionnaire was developed based on mental health literacy framework and adapted among Portuguese adolescents and young people.	Excellent	Exploratory factor analysis was conducted for each component of the questionnaire. A five-factor solution explained 46.84% of the total variance for component 1 and 40.00% for components 2 and 3. A three-factor solution explained 47.24% of the variance for component 4 and a two-factor solution explained 55.63% for component 5.	Fair	The relationship between mental health components and mental health help-seeking intention was examined using a binary logistic regression analysis. Results showed higher levels of mental health literacy tended to associate with mental health-seeking intentions.	Fair	na	na
FCCHL-AYAC (McDonald <i>et al.</i> , 2016)	The instrument was adapted from the functional, communicative, and critical health literacy scale to be suitable for adolescents and young adults diagnosed with cancer.	Good	Exploratory factor analysis was conducted for the entire scale. The screen plot suggested the extraction of three factors (53.1% variance explained)	Fair	Health literacy scores were examined by gender, whether the measure was completed online or on paper, whether the participant was on or off treatment. Results showed no significant difference was found.	Fair	na	na
ICHL (Smith <i>et al.</i> , 2016)	The instrument was developed from formative interviews with 20 deaf/hard-of hearing high school students. Also the instrument was piloted with 18 individuals including content-expert and content-	Good	na	na	The relationship between ICHL and standard health literacy measures were examined. Result showed most ICHL items were related to health literacy skills instrument-short form, s-TOFHLA, and comprehensive heart disease knowledge	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
	naïve deaf and hearing colleagues, teachers interpreters and students.				questionnaire ($p<0.05$).			
HELMA (Ghanbari <i>et al.</i> , 2016)	All items were initially generated by in-depth interviews with 67 adolescents. Then items were assessed by an expert panel review and 16 adolescents.	Good	Exploratory factor analysis was conducted and 53.37% of the variance was accounted by eight factors.	Good	na	na	na	na
HLSAC (Paakkari <i>et al.</i> , 2016)	The research team developed the HLSAC drawing on literature review, expert review and pilot test. Scale items were piloted with 401 pupils (7 th graders and 9 th graders).	Good	The five-factor structure was tested using confirmatory factor analysis (RMSEA=0.08; CFI=0.96; TLI=0.92; SRMR=0.03). However, due to high correlations between factors, one-factor structure was finally determined (RMSEA=0.08; CFI=0.94; TLI=0.92; SRMR=0.04).	Fair	Correlations were assumed between the final 10-item scale and the original 15-item scale. Results showed the 10-item HLSAC predicted approximately 97% of the variance of the 15-item instrument.	Fair	na	na
REALM-TeenS (Manganello <i>et al.</i> , 2017)	This instrument was derived from the original 66-item REALM-Teen using the item response theory. Also, ten teenage patients were piloted.	Good	na	na	The REALM-TeenS scores were correlated with the REALM-Teen ($r=0.92$, $p<0.001$). Item fit analysis using the differential item functioning showed the REALM-TeenS functioned well for different groups of sex,	Good	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
funHLS-YA (Tsubakita <i>et al.</i> , 2017)	Items were generated from health materials that were frequently used in young adults and reviewed by the research team. No target population was involved in pilot test.	Poor	1-factor model was supported by the exploratory factor analysis.	Fair	race/ethnicity, and language spoken at home.	Fair	na	na
HLS-TCO (Intarakamha ng <i>et al.</i> , 2017)	Items were developed from theories, documents and related research. Also, focus group and expert review were used to develop the instrument. 100 samples of overweight children were piloted.	Good	Confirmatory factor analysis was conducted for each subscale and results showed the model was acceptable, with factor loading ranging 0.39-0.73.	Fair	The path model of health literacy for obesity prevention behaviours was conducted using structural equation modelling. Results showed the hypothetical causal model was consistent with empirical data (chi-square=60.10, p=0.00, df=12, RMSEA=0.05, CFI=0.99; AGFI=0.99).	Fair	na	na
HLRS-Y (Bradley-Klug <i>et al.</i> , 2017)	Items were generated by focus group, expert review and a pilot test with 25 participants.	Excellent	Exploratory factor analysis was conducted, and results showed a three-factor structure of the instrument.	Fair	The relationships between health literacy scores and demographics were examined and results showed insurance type and knowledge, time since diagnosis and knowledge and self-advocacy.	Fair	na	na
p_HLAT-8 (Quemelo <i>et al.</i> , 2017)	The p_HLAT-8 was translated from the HLAT-8 according to translation procedures and was tested among 10 university	Good	Confirmatory factor analysis was conducted, and results showed the 4-factor model fit was fair	Fair	Convergent validity was examined for each sub-scale, but the results showed that only the factor 'search for information' was adequate. Discriminant	Fair	Three experts in the field of health forward and backward translated the scale independently. Ten university students	Fair

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
	students to ensure appropriateness.		(CFI=0.97, GFI=0.98, TLI=0.95, RMSEA=0.03).		validity was only adequate for two factors ('search for information' and 'understanding information').		were piloted to test and ensure the cultural congruence of the scale. Confirmatory factor analysis showed a 4-factor structure fit the model.	

Note: na, no information available. AGFI, Adjusted Goodness of Fit Index; AURA, Ask, Understand, Remember and Assessment; CFI, Comparative Fit Index; CHC Test, the Critical Health Competence Test; CHLT, Child Health Literacy Test; c-sTOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; FCCHL-AYAC, the Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; funHLS-YA, Functional Health Literacy Scale for Young Adults; HAS-A, the Health Literacy Assessment Scale for Adolescents; HELMA, the Health Literacy Measure for Adolescents; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, The Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; MaHeLi, the Maternal Health Literacy; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, the Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, the Rapid Estimate of Adolescent Literacy in Medicine Short Form; RMSEA, Root Mean Square Error of Approximation; SRMR, Standardized Root Mean Square Residual; SORT-R, Slosson Oral Reading Test-Revised; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TLI, Tucker-Lewis Index; TOFHLA, the Test of Functional Health Literacy in Adults; VOHL, the Visual Oral Health Literacy; WRAT-3, Wide-Range Achievement Test-Revised.

Appendix Table 3. The methodological quality of each study based on responsiveness for each health literacy instrument

Instrument	Responsiveness	
	Results	COSMIN score
VOHL (Ueno <i>et al.</i> , 2014)	Comparison of health literacy scores before and after health education showed both tooth and gingiva scores significantly increased after health education.	Fair

Note: As there was only one study examining the instrument's responsiveness, we only presented the instrument of VOHL. VOHL, the Visual Oral Health Literacy.

Research Checklist. PRISMA checklist for reporting systematic review

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-7
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	7
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Appendix 1 (CRD42018013759)
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8-9
Data collection process	10	Describe <u>method</u> of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9-10
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	10

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	10
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	11; Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	11; 15-16; Table 1 & 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	25; Table 3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	25; Table 4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	25; Table 5
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	25; Table 5
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	32-38
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	38-39
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	39
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

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The Quality of Health Literacy Instruments used in Children and Adolescents: A Systematic Review

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ABSTRACT

Objective: Improving health literacy at an early age is crucial to personal health and development. Although health literacy in children and adolescents has gained momentum in the past decade, it remains an under-researched area, particularly health literacy measurement. This study aimed to examine the quality of health literacy instruments used in children and adolescents and to identify the best instrument for field use.

Design: Systematic review.

Setting: A wide range of settings including schools, clinics and communities.

Participants: Children and/or adolescents aged 6-24 years.

Primary and secondary outcome measures: Measurement properties (reliability, validity and responsiveness) and other important characteristics (e.g. health topics, components or scoring systems) of health literacy instruments.

Results: There were 29 health literacy instruments identified from the screening process. When measuring health literacy in children and adolescents, researchers mainly focus on the functional domain (basic skills in reading and writing) and consider participant characteristics of developmental change (of cognitive ability), dependency (on parents) and demographic patterns (e.g. racial/ethnic backgrounds), less on differential epidemiology (of health and illness). The methodological quality of included studies as assessed via measurement properties varied from poor to excellent. More than half (62.9%) of measurement properties were unknown, due to either poor methodological quality of included studies or a lack of reporting or assessment. The 8-item Health Literacy Assessment Tool (HLAT-8) showed best evidence on construct validity and the Health Literacy Measure for Adolescents showed best evidence on reliability.

Conclusions: More rigorous and high-quality studies are needed to fill the knowledge gap in measurement properties of health literacy instruments. Although it is

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3 challenging to draw a robust conclusion about which instrument is the most reliable
4 and the most valid, this review provides important evidence that supports the use of
5 the HLAT-8 to measure childhood and adolescent health literacy in future school-
6 based research.
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11 **Keywords:** measurement properties; health literacy; children; adolescents; systematic
12 review
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For peer review only

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The COSMIN checklist was used as a methodological framework to rate the methodological quality of included studies.
- This review has updated previous three reviews of childhood and adolescent health literacy measurement tools and identified 19 additional new health literacy instruments.
- Including only studies that aimed to develop or validate a health literacy instrument may eliminate studies that used a health literacy instrument for other purposes.
- Individual subjectivity exists in the screening and data synthesis stages.

INTRODUCTION

Health literacy is a personal resource that enables an individual to make decisions for healthcare, disease prevention and health promotion in everyday life.¹ As defined by the World Health Organisation,² health literacy refers to ‘*the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health.*’ The literature has shown that health literacy is an independent and more direct predictor of health outcomes than socio-demographics.^{3 4} People with low health literacy are likely to have worse health-compromising behaviours, higher healthcare costs and poorer health status.⁵ Given the close relationship between health literacy and health outcomes, many countries have adopted health literacy promotion as a key strategy to reduce health inequities.⁶

From a health promotion perspective, improving health literacy at an early age is crucial to childhood and adolescent health and development.⁷ As demonstrated by Diamond *et al.*⁸ and Robinson *et al.*,⁹ health literacy interventions for children and adolescents can bring about improvements in healthy behaviours and decreased use of emergency department services. Although health literacy in young people has gained increasing attention, with a rapidly growing number of publications in the past decade,¹⁰⁻¹³ childhood and adolescent health literacy is still under-researched. According to Forrest *et al.*'s 4D model,^{14 15} health literacy in children and adolescents is mediated by four additional factors compared to adults: (1) *developmental* change: children and adolescents have less well-developed cognitive ability than adults; (2) *dependency*: children and adolescents depend more on their parents and peers than adults do; (3) *differential* epidemiology: children and adolescents experience a unique pattern of health, illness and disability; and (4) *demographic* patterns: many children and adolescents living in poverty or in single-parent families are neglected and so require additional care. These four differences pose significant challenges for researchers when measuring health literacy in children and adolescents.

Health literacy is a broad and multi-dimensional concept with varying definitions.¹⁶ This paper uses the definition by Nutbeam who states that health literacy consists of three domains: functional, interactive and critical.¹⁷ The *functional* domain refers to

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3 basic skills in reading and writing health information, which are important for
4 functioning effectively in everyday life. The *interactive* domain represents advanced
5 skills that allow individuals to extract health information and derive meaning from
6 different forms of communication. And the *critical* domain represents more advanced
7 skills that can be used to critically evaluate health information and take control over
8 health determinants.¹⁷ Although health literacy is sufficiently explained in terms of its
9 definitions¹⁷⁻¹⁹ and theoretical models,^{4,7} its measurement remains a contested issue.
10 There are two possible reasons for this. One reason is the large variety of health
11 literacy definitions and conceptual models,^{12,16} and the other reason is that researchers
12 may have different study aims, populations and contexts when measuring health
13 literacy.^{20,21}

22 Currently, there are three systematic reviews describing and analysing the
23 methodology and measurement of childhood and adolescent health literacy.^{10,11,13} In
24 2013, Ormshaw *et al.*¹⁰ conducted a systematic review of child and adolescent health
25 literacy measures. This review used four questions to explore health literacy
26 measurement in children and adolescents: “*What measurement tools were used? What*
27 *health topics were involved? What components were identified? and Did studies*
28 *achieve their stated aims?*” The authors identified 16 empirical studies, with only six
29 of them evaluating health literacy measurement as their primary aim. The remaining
30 studies used health literacy measures as either a comparison tool when developing
31 other new instruments or as a dependent variable to examine the effect of an
32 intervention program. Subsequently, in 2014, Perry¹¹ conducted an integrative review
33 of health literacy instruments used in adolescents. In accordance with the eligibility
34 criteria, five instruments were identified. More recently, Okan *et al.*¹³ conducted
35 another systematic review on generic health literacy instruments used for children and
36 adolescents with the aim of identifying and assessing relevant instruments for first-
37 time use. They found fifteen generic health literacy instruments used for this target
38 group.

50 Although these three reviews provide general knowledge about the methodology and
51 measurement of health literacy in young people, they all have limitations. Ormshaw *et*
52 *al.*¹⁰ did not evaluate measurement properties of each health literacy instrument.
53 Although Perry¹¹ and Okan *et al.*¹³ summarised measurement properties of each
54 instrument.

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3 instrument, the information provided was limited, mostly descriptive, and lacked a
4 critical appraisal. Notably, none of the three reviews considered the methodological
5 quality of included studies^{10 11 13}. A lack of quality assessment of studies raises
6 concerns about the utility of such reviews for evaluating and selecting health literacy
7 instruments for children and adolescents. Therefore, it is still unclear which
8 instrument is the best in terms of its validity, reliability and feasibility for field use. In
9 addition, it is also unclear how Nutbeam's three-domain health literacy model and
10 Forrest *et al.*'s 4D model are considered in existing health literacy instruments for
11 children and adolescents.
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19 To fill these knowledge gaps, this systematic review aimed to examine the quality of
20 health literacy instruments used in the young population and to identify the best
21 instrument for field use. We expect the findings will assist researchers in identifying
22 and selecting the most appropriate instrument for different purposes when measuring
23 childhood and adolescent health literacy.
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28 **METHODS**

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32 Following the methods for conducting systematic reviews outlined in the Cochrane
33 Handbook,²² we developed a review protocol (See **Appendix 1**, PROSPERO
34 registered ID: CRD42018013759) prior to commencing the study. The Preferred
35 Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement²³
36 (See **Research Checklist**) was used to ensure the reporting quality of this review.
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41 **Literature search**

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45 The review took place over two time periods: The initial systematic review covered
46 the period between 1 January 1974 and 16 May 2014 (period 1). The start date of
47 1974 was chosen because this was the date from which the term '*health literacy*' was
48 first used.²⁴ A second search was used to update the review in February 2018. It
49 covered the period 17 May 2014 to 31 Jan 2018 (period 2). The databases searched
50 were: Medline, PubMed, Embase, PsycINFO, CINAHL, ERIC and the Cochrane
51 Library. The search strategy was designed on the basis of previous reviews^{5 10 25 26} and
52 in consultation with two librarian experts. Three types of search terms were used: (1)
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3 construct-related terms: ‘*health literacy*’ OR ‘*health and education and literacy*’; (2)
4 outcome-related terms: ‘*health literacy assess**’ OR ‘*health literacy measure**’ OR
5 ‘*health literacy evaluat**’ OR ‘*health literacy instrument**’ OR ‘*health literacy tool**’;
6 and (3) age-related terms: ‘*child**’ OR ‘*adolescent**’ OR ‘*student**’ OR ‘*youth*’ OR
7 ‘*young people*’ OR ‘*teen**’ OR ‘*young adult.*’
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12 No language restriction was applied. The detailed search strategy for each database is
13 available in **Appendix 2**. As per the PRISMA flow diagram,²³ the references from
14 included studies and from six previously published systematic reviews on health
15 literacy^{5 10 25-28} were also included.
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19 20 **Eligibility criteria**

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23 Studies had to fulfil the following criteria to be included: (1) the stated aim of the
24 study was to develop or validate a health literacy instrument; (2) participants were
25 children or adolescents aged 6 to 24. This broad age range was used because the age
26 range for ‘*children*’ (under the age of 18) and ‘*adolescents*’ (aged 10 to 24) overlap²⁹
27 and also because children aged over 6 are able to learn and develop their own health
28 literacy³⁰; (3) the term ‘*health literacy*’ was explicitly defined, although studies
29 assessing health numeracy (the ability to understand and use numbers in healthcare
30 settings) were also considered; and (4) at least one measurement property (reliability,
31 validity and responsiveness) was reported in the outcomes.
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40 Studies were excluded if: (a) the full paper was not available (i.e. only a conference
41 abstract or protocol was available); (b) they were not peer-reviewed (e.g. dissertations,
42 government reports); or (c) they were qualitative studies.
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46 **Selection process**

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49 All references were imported into EndNote X7 software (Thomson Reuters, New
50 York, NY) and duplicate records were initially removed before screening. Next, one
51 author (GS) screened all studies based on title and abstract. Full-text papers of the
52 remaining titles and abstracts were then obtained separately for each review round
53 (period 1 and period 2). All papers were screened by two independent authors (GS
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3 and SA). At each major step of this systematic review, discrepancies between authors
4 were resolved through discussion.
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7 8 **Data extraction** 9

10 The data that were extracted from papers were: characteristics of included studies (e.g.
11 first author, published year and country), general characteristics of instruments (e.g.
12 health topics, components and scoring systems), methodological quality of the study
13 (e.g. internal consistency, reliability and measurement error) and ratings of
14 measurement properties of included instruments (e.g. internal consistency, reliability
15 and measurement error). Data extraction from full-text papers published during period
16 1 was performed by two independent authors (GS and TS), whereas data extraction
17 from full-text papers published during period 2 was conducted by one author (GS)
18 and then checked by a second author (TS).
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27 **Methodological quality assessment of included studies** 28 29

30 The methodological quality of included studies was assessed using the COnsensus-
31 based Standards for the selection of health Measurement Instruments (COSMIN)
32 checklist.³¹ The COSMIN checklist is a critical appraisal tool containing standards for
33 evaluating the methodological quality of studies on measurement properties of health
34 measurement instruments.³² Specifically, nine measurement properties (internal
35 consistency, reliability, measurement error, content validity, structural validity,
36 hypotheses testing, cross-cultural validity, criterion validity and responsiveness) were
37 assessed.³² Since there is no agreed-upon ‘gold standard’ for health literacy
38 measurement,^{33 34} criterion validity was not assessed in this review. Each
39 measurement property section contains 5 to 18 evaluating items. For example,
40 ‘internal consistency’ is evaluated against 11 items. Each item is scored using a four-
41 point scoring system (‘excellent’, ‘good’, ‘fair’ or ‘poor’). The overall
42 methodological quality of a study is obtained for each measurement property
43 separately, by taking the lowest rating of any item in that section (i.e. ‘worst score
44 counts’). Two authors (GS and TS) independently assessed the methodological
45 quality of included studies published during period 1, whereas the quality of included
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3 studies published during period 2 was assessed by one author (GS) and then checked
4 by another (TS).
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7 **Evaluation of measurement properties for included instruments**

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10 The quality of each measurement property of an instrument was evaluated using
11 quality criteria proposed by Terwee *et al.*³⁵, who are members of the group that
12 developed the COSMIN checklist (See **Appendix 3**). Each measurement property was
13 given a rating result ('+' positive, '-' negative, '?' indeterminate and 'na' no
14 information available).
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19 **Best evidence synthesis: levels of evidence**

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22 As recommended by the COSMIN checklist developer group,³² '*a best evidence*
23 *synthesis*' was used to synthesise all the evidence on measurement properties of
24 different instruments. The procedure used was similar to the Grading of
25 Recommendations, Assessment, Development and Evaluation (GRADE) framework³⁶,
26 a transparent approach to rating quality of evidence that is often used in reviews of
27 clinical trials.³⁷ Given that this review did not target clinical trials, the GRADE
28 framework adapted by the COSMIN group was used.³⁸ Under this procedure, the
29 possible overall rating for a measurement property is '*positive*', '*negative*',
30 '*conflicting*' or '*unknown*', accompanied by levels of evidence ('*strong*', '*moderate*'
31 or '*limited*') (See **Appendix 4**). Three steps were taken to obtain the overall rating for
32 a measurement property. First, the methodological quality of a study on each
33 measurement property was assessed using the COSMIN checklist. Measurement
34 properties from '*poor*' methodological quality studies did not contribute to '*the best*
35 *evidence synthesis*'. Second, the quality of each measurement property of an
36 instrument was evaluated using Terwee's quality criteria.³⁵ Third, the rating results of
37 measurement properties in different studies on the same instrument were examined
38 whether consistent or not. This best evidence synthesis was performed by one author
39 (GS) and then checked by a second author (TS).
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54 **Patient and Public Involvement**

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3 Children and adolescents were not involved in setting the research question, the
4 outcome measures, or the design or implementation of this study.
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7 8 **Results** 9

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11 The initial search identified 2790 studies. After duplicates and initial title/abstract
12 screening, 361 full-text articles were identified and obtained. As per the eligibility
13 criteria, 29 studies were included,³⁹⁻⁵³ yielding 29 unique health literacy instruments
14 used in children and adolescents (See **Figure 1**).
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17 18 **Characteristics of included studies** 19

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21 Of the 29 studies identified, 25 were published between 2010 and 2017 (See **Table 1**).
22 Most included studies were conducted in Western countries (n=20), with eleven
23 studies carried out in the USA. The target population (aged 7 to 25) could be roughly
24 classified into three subgroups: children aged 7 to 12 (n=5), adolescents aged 13 to 17
25 (n=20) and young adults aged 18 to 25 (n=4). Schools (n=17) were the most common
26 recruitment settings, compared to clinical settings (n=8) and communities (n=4).
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Table 1. Characteristics of included studies

Study no	Author (Year)	Country	Target population	Health literacy instrument	Sample size (% male)	Sampling method	Recruitment setting
1	Davis <i>et al.</i> ⁴¹ (2006)	USA	Adolescents aged 10-19 years (mean age=14.8±1.9)	REALM-Teen	1533 (47.4)	na	Middle schools, high schools, paediatric primary care clinic and summer programs
2	Norman and Skinner ⁴³ (2006)	Canada	Adolescents aged 13-21 years (mean age=14.95±1.24)	eHEALS	664 (55.7)	Sampling from one arm of a randomized controlled trial	Secondary schools
3	Chisolm and Buchanan ⁴⁸ (2007)	USA	Young people aged 13-17 years (mean age=14.7)	TOFHLA	50 (48.0)	na	Children's hospital
4	Steckelberg <i>et al.</i> ⁴⁷ (2009)	Germany	Students in Grade 10-11 and university	CHC Test	Sample 1: 322 (36.6) Sample 2: 107 (32.7)	na	Secondary schools, university
5	Schmidt <i>et al.</i> ⁴⁶ (2010)	Germany	Children aged 9-13 years (mean age=10.4)	HKACSS	852 (52.9)	na	Primary school
6	Wu <i>et al.</i> ⁴⁰ (2010)	Canada	Students in Grade 8-12	HLAB	275 (48.0)	Convenience sampling	Secondary schools
7	Levin-Zamir <i>et al.</i> ⁴⁹ (2011)	Israel	Adolescents in Grade 7, 9, 11 (approximately age 13, 15 and 17)	MHL	1316 (52.0)	Probability sampling and random cluster sampling	Public schools
8	Chang <i>et al.</i> ⁵¹ (2012)	Taiwan	Students in high school (mean age=16.01±1.02)	c-sTOFHLAd	300 (52.6)	Multiple-stage stratified random sampling	High schools
9	Hoffman <i>et al.</i> ⁵⁰ (2013)	USA	Youth aged 14-19 years (mean age=17)	REALM-Teen; NVS; s-TOFHLA	229 (61.6)	na	Private high school
10	Massey <i>et al.</i> ⁴⁴ (2013)	USA	Adolescents aged 13-17 years (mean age=14.8)	MMAHL	1208 (37.6)	Sampling from a large health insurance network	Publicly health insurance network
11	Mulvaney <i>et al.</i> ⁵³ (2013)	USA	Adolescents aged 12-17 years (Sample 1: mean age=13.92; Sample 2: mean age=15.10)	DNT-39 and DNT-14	Sample 1: 61 (52.5) Sample 2: 72 (55.6)	na	Diabetes clinics

Study no	Author (Year)	Country	Target population	Health literacy instrument	Sample size (% male)	Sampling method	Recruitment setting
12	Abel <i>et al.</i> ⁴⁵ (2014)	Switzerland	Young adults aged 18-25 years (male mean age: 19.6; female mean age=18.8)	HLAT-8	7428 (95.5)	Sampling from compulsory military service for males and two-stage random sampling for females	Compulsory military service, communities
13	Driessnack <i>et al.</i> ⁵⁴ (2014)	USA	Children aged 7-12 years	NVS	47 (53.0)	Convenience sampling	The science centre
14	Harper ⁴² (2014)	New Zealand	Students aged 18-24 years	HLAT-51	144 (41.0)	Purposeful sampling	College
15	Warsh <i>et al.</i> ³⁹ (2014)	USA	Children aged 7-17 years (median age=11)	NVS	97 (46.0)	Convenience sampling	Paediatric clinics
16	Liu <i>et al.</i> ⁵⁵ (2014)	Taiwan	Children in grade six	CHLT	162609 (51.1)	National sampling	Primary schools
17	Ueno <i>et al.</i> ⁵⁶ (2014)	Japan	Students in high school Grade 1 (age range: 15-16 years)	VOHL	162 (46.3)	Convenience sampling	A senior high school
18	Manganello <i>et al.</i> ⁵⁷ (2015)	USA	Youth aged 12-19 years (mean age=15.6)	HAS-A	272 (37.0)	Convenience sampling	A paediatric clinic and the community
19	Naigaga <i>et al.</i> ⁵⁸ (2015)	Uganda	Pregnant adolescents aged 15-19 years	MaHeLi	384 (0)	Random sampling	Health centres
20	de Jesus Loureiro <i>et al.</i> ⁵⁹ (2015)	Portugal	Adolescents and young people aged 14-24 years (mean age=16.75±1.62)	QuALiSMental	4938 (43.3)	Multi-stage cluster random sampling	Schools
21	McDonald <i>et al.</i> ⁶⁰ (2016)	Australia	Adolescents and young adults diagnosed with cancer (age range: 12-24 years)	FCCHL-AYAC	105 (33.3)	Sampling from a support organisation	An organisation for young people living with cancer
22	Smith <i>et al.</i> ⁶¹ (2016)	USA	Deaf/hard-of hearing and hearing adolescents in high school (mean age=17.0±0.84 and 15.8±1.1)	ICHL	Sample 1: 154 (53.2) Sample 2: 89 (33.0)	Convenience sampling	Medical centre summer programs
23	Ghanbari <i>et al.</i> ⁶² (2016)	Iran	Adolescents aged 15-18 years (mean age=16.2±1.03)	HELMA	582 (48.8)	Multi-stage sampling	High schools
24	Paakkari <i>et al.</i> ⁶³ (2016)	Finland	Pupils (7 th graders aged 13 years: n=1918; 9 th graders aged 15 years: n=1935)	HLSAC	3853 (na)	Cluster sampling	Secondary schools
25	Manganello <i>et al.</i>	USA	Adolescents aged 14-19 years	REALM-TeenS	174 (na)	na	Adolescent medicine

Study no	Author (Year)	Country	Target population	Health literacy instrument	Sample size (% male)	Sampling method	Recruitment setting
26	<i>al.</i> ⁶⁴ (2017) Tsubakita <i>et al.</i> ⁶⁵ (2017)	Japan	(mean age=16.6) Young adults aged 18-26 years (mean age=19.65±1.34)	funHLS-YA	1751 (76.8)	Convenience sampling	clinics A private university
27	Intarakamhang <i>et al.</i> ⁶⁶ (2017)	Thailand	Overweight children aged 9-14 years	HLS-TCO	2000 (na)	Quota-stratified random sampling	Schools
28	Bradley-Klug <i>et al.</i> ⁶⁷ (2017)	USA	Youth and young adults with chronic health conditions aged 13-21 years (mean age=17.6)	HLRS-Y	204 (24.3)	National sampling	Community-based agencies and social media outlets
29	Quemelo <i>et al.</i> ⁶⁸ (2017)	Brazil	University students (mean age=22.7±5.3)	p_HLAT-8	472 (33.9)	na	A university

Note: na, no information available. CHC Test, Critical Health Competence Test; CHLT, Child Health Literacy Test; c-STOFHLAd, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; funHLS-YA, Functional Health Literacy Scale for Young Adults; HAS-A, Health Literacy Assessment Scale for Adolescents; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, 8-item Health Literacy Assessment Tool; HLAT-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; VOHL, Visual Oral Health Literacy.

General characteristics of included instruments

Compared to previous systematic reviews,^{10 11 13} this review identified 19 additional new health literacy instruments (eHEALS, s-TOFHLA, DNT-39, DNT-14, HLAT-51, HLAT-8, CHLT, VOHL, HAS-A, QuALiSMental, FCCHL-AYAC, ICHL, HELMA, HLSAC, REALM-TeenS, funHLS-YA, HLS-TCO, HLRS-Y and p_HLAT-8). The 29 health literacy instruments were classified into three groups based on whether the instrument was developed bespoke for the study or not (See **Table 2**).¹⁰ The three groups were: (1) newly-developed instruments for childhood, adolescent and youth health literacy (n=20),^{40-47 49 50 55-58 61-63 65-67} (2) adapted instruments that were based on previous instruments for adult/adolescent health literacy (n=6),^{51 53 59 60 64 68} and (3) original instruments that were developed for adult health literacy (n=3).^{39 48 50 52}

Health literacy domains and components

Next, Nutbeam's three-domain health literacy model¹⁷ was used to classify the 29 instruments according to which of the commonly-used components of health literacy were included. Results showed that ten instruments measured only functional health literacy^{39 41 48 50-53 56 64 65} and one instrument measured only critical health literacy.⁴⁷ There was one instrument measuring functional and interactive health literacy⁴⁶, one measuring functional and critical health literacy⁴⁰, and one measuring interactive and critical health literacy.⁶¹ Fifteen instruments measured health literacy by all three domains (functional, interactive and critical).^{42-45 49 55 57-60 62 63 66-68}

Consideration of participants' characteristics

As per Forrest *et al.*'s 4D model,^{14 15} the 29 included instruments were examined for whether participant characteristics were considered when developing a new instrument or validating an existing instrument. Results showed most of the health literacy instruments considered developmental change, dependency and demographic patterns. In contrast, only seven instruments considered differential epidemiology.^{53 58}
^{60 61 66 67}

Health topics, contents and readability levels

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3 Health literacy instruments for children and adolescents covered a range of health
4 topics such as nutrition and sexual health. Most instruments (n=26) measured health
5 literacy in healthcare settings or health promotion contexts (e.g. general health topics,
6 oral health, or mental health), while only three instruments measured health literacy in
7 the specific context of eHealth or media health.^{42 43 49} In relation to the readability of
8 tested materials, only eight health literacy instruments reported their readability levels,
9 ranging from 2th to 19.5th grade.
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15 Burden and forms of administration

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18 The time to administer was reported in seven instruments, ranging from 3 to 90
19 minutes. There were three forms of administration: self-administered instruments
20 (n=19), interviewer-administered instruments (n=9), and video-assisted, interviewer-
21 administered instruments (n=1). Regarding the method of assessment, fifteen
22 instruments were performance-based, eleven instruments were self-report, and three
23 included both performance-based and self-report items.
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Table 2. General and important characteristics of included instruments used in children and adolescents

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
1	NVS ^{50,54,39}	Functional HL 1. Reading comprehension (2) 2. Numeracy (4)	Demographic patterns	Nutrition-related information about the label of an ice cream container (na)	Open-ended	Score range: 0-6; Ordinal category: 0-1: high likelihood of limited literacy; 2-3: possibility of limited literacy; 4-6: adequate literacy	No longer than 3 minutes	Interviewer-administered & Performance-based
2	TOFHLA ⁴⁸	Functional HL 1. Reading comprehension (50) 2. Numeracy (17)	Developmental change Demographic patterns	Instruction for preparation for an upper gastrointestinal series (4.3 grade), a standard informed consent form (10.4 grade), patients' rights and responsibilities section of a Medicaid application form (19.5 grade), actual hospital forms & labelled prescription vials (9.4 grade)	4 response options	Score range: 0-100; Ordinal category: 0-59: inadequate health literacy; 60-74: marginal health literacy; 75-100: adequate health literacy	12.9 minutes (8.9-17.3 minutes)	Interviewer-administered & Performance-based
3	s-TOFHLA ⁵⁰	Functional HL 1. Reading comprehension (36)	Demographic patterns	Instruction for preparation for an upper gastrointestinal series (4 th grade), patients' rights and responsibilities section of a Medicaid application form (10 th grade)	4 response options	Score range: 0-36; Ordinal category: 0-16: inadequate literacy; 17-22: marginal literacy; 23-36: adequate literacy	na	Interviewer-administered & Performance-based
4	c-sTOFHLa ⁵¹	Functional HL 1. Reading comprehension (36)	Developmental change Demographic patterns	Instruction for preparation for an upper gastrointestinal series (4 th grade), patients' rights and responsibilities section of a Medicaid application form (10 th grade)	4 response options	Score range: 0-36; Ordinal category: 0-16: inadequate literacy; 17-22: marginal literacy; 23-36: adequate literacy	20-minute class period	Self-administered & Performance-based
5	REALM-Teen ^{41,50}	Functional HL 1. Reading recognition (66)	Developmental change Demographic patterns	66 health-related words such as weight, prescription and tetanus (6 th grade)	Open-ended	Score range: 0-66; Ordinal category: 0-37: ≤ 3 rd ; 38-47: 4 th -	2-3 minutes	Interviewer-administered & Performance-

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
						5 th ; 48-58: 6 th -7 th ; 59-62: 8 th -9 th ; 63-66: ≥ 10 th		based
6	HLAB ⁴⁰	Functional and critical HL 1. Understanding health information (30) 2. Evaluating health information (17)	Developmental change Demographic patterns	A range of topics such as nutrition and sexual health (pilot-tested)	Open-ended	Score range: 0-107; Continuous score	Two regular classroom sessions	Self-Administered & Performance-based
7	MMAHL ⁴⁴	Functional, interactive and critical HL 1. Patient-provider encounter (4) 2. Interaction with the health care system (5) 3. Rights and responsibilities (7) 4. Confidence in using health information from personal source (3) 5. Confidence in using health information from media source (3) 6. Health information seeking competency using the Internet (2)	Developmental change Demographic patterns Dependency	Experiences of how to access, navigate and manage one's health care and preventive health needs (6 th grade)	5-point Likert scale	Score range: na; Continuous score	na	Self-administered & Self-reported
8	MHL ⁴⁹	Functional, interactive and critical HL 1. Content identification (6) 2. Perceived influence on behaviour (6) 3. Critical analysis and intended (6)	Dependency Demographic patterns	Nutrition/dieting, physical activity, body image, sexual activity, cigarette smoking, alcohol consumption, violent behaviour, safety habits and/or friendship and family connectedness (pilot-tested)	Open-ended & multiple choice	Score range: 0-24; Continuous score	na	Video-assisted interviewer-administered & Performance-based

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
9	DNT-39 ⁵³	4. Action/reaction (6) Functional health literacy 1. Health numeracy (39)	Differential epidemiology Demographic patterns	Nutrition, exercise, blood glucose monitoring and insulin administration (na)	Open-ended	Score range: 0-100; Continuous score	na	Interviewer-administered & Performance-based
10	DNT-14 ⁵³	Functional health literacy 1. Health numeracy (14)	Differential epidemiology Demographic patterns	Nutrition, exercise, blood glucose monitoring and insulin administration (na)	Open-ended	Score range: 0-100; Continuous score	na	Interviewer-administered & Performance-based
11	eHEALS ⁴³	Functional, interactive and critical HL 1. Accessing health information (4) 2. Evaluating health information (2) 3. Applying health information (2)	Developmental change Dependency Demographic patterns	General health topics about online health information (pilot-tested)	5-point Likert scale	Score range: na; Continuous score	na	Self-Administered & Self-reported
12	CHC Test ⁴⁷	Critical HL 1. Understanding medical concepts (15) 2. Searching literature skills (22) 3. Basic statistics (18) 4. Design of experiments and sampling (17)	Developmental change Demographic patterns	Echinacea and common cold, magnetic resonance imaging in knee injuries, treatment of acne, breast cancer screening (pilot-tested)	Open-ended & multiple choice	na	Less than 90 minutes	Interviewer-administered & Performance-based
13	HKACSS ⁴⁶	Functional and interactive HL 1. Health knowledge (3) 2. Health attitudes (4) 3. Health communication (3) 4. Self-efficacy (3)	Developmental change Dependency Demographic patterns	Physical activities, nutrition, smoking, vaccination, tooth health and general health (na)	2 response options; 5-point Likert scale; 4-point Likert	Score range: na; Continuous score	na	Self-Administered & Performance-based & Self-reported

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
14	HLAT-51 ⁴²	Functional, interactive and critical HL 1. Comprehension skill (20) 2. Health numeracy (11) 3. Media literacy (8) 4. Digital literacy (12)	Developmental change Dependency Demographic patterns	Health topics such as gout and uric acid, high cholesterol and triglyceride levels, health-information-seeking skills (na)	scale Yes/no; multiple choice	na	30-45 minutes	Self-administered & Performance-based & Self-reported
15	HLAT-8 ⁴⁵	Functional, interactive and critical HL 1. Understanding health information (2) 2. Finding health information (2) 3. Interactive health literacy (2) 4. Critical health literacy (2)	Dependency Demographic patterns	General health topics in people's daily life (na)	5-point Likert scale; 4- point Likert scale	Score range: 0-37; Continuous score	na	Self-administered & Self-reported
16	CHLT ⁵⁵	Functional, interactive and critical HL 1. Health knowledge (11) 2. Health attitude (16) 3. Health skills (5)	Developmental change Dependency Demographic patterns	Personal hygiene, growth and aging, sexual education and mental health, healthy eating, safety and first aid, medicine safety, substance abuse prevention, health promotion and disease prevention, consumer health, health and environment (pilot-tested)	Multiple choice	Score range: 0-32; Continuous score	na	Self-administered & Performance-based
17	VOHL ⁵⁶	Functional HL 1. Health knowledge (2)	Developmental change	Oral health for tooth & gingiva (na)	Visual drawing	Score range: 0-6; Continuous score	na	Self-administered & Performance-based
18	HAS-A ⁵⁷	Functional, interactive and	Developmental change	General health topics in daily	5-point	Score range: 0-24	na	Self-

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
		critical HL	Demographic patterns	life (pilot-tested)	Likert scale	(understanding), 0-20 (communication), 0-16 (confusion); Continuous score		administered & Self-reported
		1. Understanding health information (6)	Dependency					
		2. Communication health information (5)						
		3. Confusion about health information (4)						
19	MaHeLi ⁵⁸	Functional, interactive and critical HL	Developmental change	General health and maternal health topics (na)	6-point Likert scale	na	na	Interviewer-administered & Self-reported
		1. Health seeking-behaviour (1)	Demographic patterns					
		2. Competence and coping skills (6)	Dependency					
		3. Appraisal of health information (5)	Differential epidemiology					
20	QuALiSMental ⁵⁹	Functional, interactive and critical HL	Developmental change	Mental health vignettes (na)	Yes/no; Multiple choice	na	40-50 minutes	Self-administered & Performance-based
		1. Recognition disorders (14)	Demographic patterns					
		2. Knowledge about the professionals and treatments available (16)	Dependency					
		3. Knowledge of the effectiveness of self-help strategies (12)						
		4. Knowledge and skills needed to provide support and first aid to others (10)						
		5. Knowledge of how to prevent mental disorders (8)						

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
21	FCCHL-AYA ⁶⁰	Functional, interactive and critical HL 1. Functional HL (6) 2. Communicative HL(3) 3. Critical HL (4)	Developmental change Dependency Differential epidemiology	Health topics regarding cancer in daily life (2 nd grade)	4-point Likert scale	Score range: 13-52; Continuous score	na	Self-administered & Self-reported
22	ICHL ⁶¹	Interactive and critical HL 1. Interactive HL (2) 2. Critical HL (7)	Developmental change Demographic patterns Dependency Differential epidemiology	General health topics in daily life (pilot-tested)	5-point Likert scale	na	40-55 minutes (together with other measures)	Self-administered & Self-reported
23	HELMA ⁶²	Functional, interactive and critical HL 1. Access (5) 2. Reading (5) 3. Understanding (10) 4. Appraise (5) 5. Use (4) 6. Communication (8) 7. Self-efficacy (4) 8. Numeracy (3)	Developmental change Dependency	General health topics in daily life (pilot-tested)	5-point Likert scale	Score range: 0-100; Ordinal category: 0-50: inadequate; 50.1-66: problematic; 66.1-84: sufficient; 84.1-100: excellent	15 minutes	Self-administered & Self-reported
24	HLSAC ⁶³	Functional, interactive and critical HL 1. Theoretical knowledge (2) 2. Practical knowledge (2) 3. Individual critical thinking (2) 4. Self-awareness (2) 5. Citizenship (2)	Developmental change Dependency	General health topics in daily life (7 th grade)	4-point Likert scale	na	45 minutes (together with the HBSC survey)	Self-administered & Self-reported
25	REALM-Teens ⁶⁴	Functional HL 1. Reading recognition (10)	Developmental change Demographic patterns	10 health-related words such as diabetes (6 th grade)	Open-ended	Score range: 0-10; Ordinal category: 0-2: ≤ 3 rd ; 3-4: 4 th -5 th ; 5-6: 6 th -7 th ; 7-8: 8 th -	13.6 seconds (range: 7.8-23.0)	Interviewer-administered & Performance-based

No	HL instrument	HL domain and component (item number)	Participant characteristics and consideration	Health topic and content (readability level)	Response category	Scoring system	Burden	Administration form
26	funHLS-YA ⁶⁵	Functional HL 1. Word recognition and comprehension (19)	Developmental change	Diseases and symptoms, nutrition and diet, biology of the human body (na)	Multiple choice	9 th ; 9-10: ≥ 10 th Score range: na; Continuous score	5 minutes	Self-administered & Performance-based
27	HLS-TCO ⁶⁶	Functional, interactive and critical HL 1. Health knowledge and understanding (10) 2. Accessing information and services (5) 3. Communicating skills (6) 4. Managing health conditions (5) 5. Media literacy (5) 6. Making decisions (4)	Developmental change Demographic patterns Dependency Differential epidemiology	Health information for obesity preventive behaviours (pilot-tested)	Multiple choice; Likert scale	Score range: 0-135; Ordinal category: low: <21 for FHL, <33 for IHL, <27 for CHL; fair: 21-27.99 for FHL, 33-43.99 for IHL, 27-35.99 for CHL; high: 28-35 for FHL, 44-54.9 for IHL, 36-45 for CHL	na	Self-administered & Performance-based & Self-reported
28	HLRS-Y ⁶⁷	Functional, interactive and critical HL 1. Knowledge (10) 2. Self-advocacy/support (14) 3. Resiliency (13)	Developmental change Demographic patterns Differential epidemiology	Health information about chronic health conditions (pilot-tested)	4-point Likert scale	Score range: na; Continuous score	15-20 minutes	Self-administered & Self-reported
29	p_HLAT-8 ⁶⁸	Functional, interactive and critical HL 1. Understanding health information (2) 2. Searching health information (2) 3. Communicating health information (2) Appraising health information (2)	Dependency	General health topics in daily life (pilot-tested)	5-point Likert scale; 4-point Likert scale	Score range: 0-37; Continuous score	na	Self-administered & Self-reported

Note: na, no information available. CHC Test, Critical Health Competence Test; CHLT, Child Health Literacy Test; c-sTOFHLAd, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; funHLS-YA, Functional Health Literacy Scale for Young Adults; HAS-A, Health Literacy Assessment Scale for Adolescents; HBSC, Health Behaviour in School-aged Children; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HL, Health Literacy; HLAB, Health Literacy Assessment Booklet; HLAT-8, 8-item Health Literacy Assessment Tool; HLAT-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; VOHL, Visual Oral Health Literacy.

Evaluation of methodological quality of included studies

According to the COSMIN checklist, the methodological quality of each instrument as assessed by each study is presented in **Table 3**. Almost all studies (n=28) examined content validity, 24 studies assessed internal consistency and hypotheses testing, 17 studies examined structural validity, eight studies assessed test-retest/inter-rater reliability, two studies assessed cross-cultural validity and only one study assessed responsiveness.

Evaluation of instruments' measurement properties

After the methodological quality assessment of included studies, measurement properties of each health literacy instrument were examined according to Terwee's quality criteria (See **Appendix 5**).³⁵ The rating results of measurement properties of each instrument are summarised in **Table 4**.

The synthesised evidence for the overall rating of measurement properties

Finally, a synthesis was conducted for the overall rating of measurement properties for each instrument according to '*the best evidence synthesis*' guidelines recommended by the COSMIN checklist developer group.³² This synthesis result was derived from information presented in **Table 3** and **Table 4**. The overall rating of each measurement property for each health literacy instrument is presented in **Table 5**. In summary, most information (62.9%, 146/232) on measurement properties was unknown due to either poor methodological quality of studies or a lack of information on reporting or assessment.

Table 3. Methodological quality of each study for each measurement property according to the COSMIN checklist

Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsive-ness
					Structural validity	Hypotheses testing	Cross-cultural validity	
NVS (Hoffman <i>et al.</i> , 2013) ⁵⁰	Poor	na	na	Poor	na	Fair	na	na
NVS (Driessnack <i>et al.</i> , 2014) ⁵⁴	Poor	na	na	Poor	na	Poor	na	na
NVS (Warsh <i>et al.</i> , 2014) ³⁹	na	na	na	Poor	na	Fair	na	na
TOFHLA (Chisolm and Buchanan, 2007) ⁴⁸	na	na	na	Poor	na	Fair	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013) ⁵⁰	Poor	na	na	Poor	na	Fair	na	na
c-sTOFHLAd (Chang <i>et al.</i> , 2012) ⁵¹	Fair	Fair	na	Good	Fair	Fair	Fair	na
REALM-Teen (Davis <i>et al.</i> , 2006) ⁴¹	Poor	Fair	na	Good	na	Fair	na	na
REALM-Teen (Hoffman <i>et al.</i> , 2013) ⁵⁰	Poor	na	na	Poor	na	Poor	na	na
HLAB (Wu <i>et al.</i> , 2010) ⁴⁰	Fair	Poor	na	Good	na	Fair	na	na
MMAHL (Massey <i>et al.</i> , 2013) ⁴⁴	Good	na	na	Good	Good	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011) ⁴⁹	Poor	na	na	Good	na	Good	na	na
DNT-39 (Mulvaney <i>et al.</i> , 2013) ⁵³	Fair	na	na	Poor	na	Fair	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013) ⁵³	Fair	na	na	Poor	na	Fair	na	na
eHEALS (Norman <i>et al.</i> , 2006) ⁴³	Fair	Fair	na	Good	Fair	Fair	na	na
CHC Test (Steckelberg <i>et al.</i> , 2009) ⁴⁷	na	Poor	na	Good	Poor	na	na	na
HKACSS (Schmidt <i>et al.</i> , 2010) ⁴⁶	Excellent	na	na	Good	na	Good	na	na
HLAT-51 (Harper, 2014) ⁴²	Poor	na	na	Good	Poor	na	na	na
HLAT-8 (Abel <i>et al.</i> , 2014) ⁴⁵	Excellent	na	na	Poor	Excellent	Good	na	na
CHLT (Liu <i>et al.</i> , 2014) ⁵⁵	Fair	na	na	Good	Fair	Fair	na	na
VOHL (Ueno <i>et al.</i> , 2014) ⁵⁶	na	Fair	na	na	na	Fair	na	Fair
HAS-A (Manganello <i>et al.</i> 2015) ⁵⁷	Fair	na	na	Good	Fair	Fair	na	na
MaHeLi (Naigaga <i>et al.</i> 2015) ⁵⁸	Fair	na	na	Poor	Fair	na	na	na
QuALiSMental (de Jesus Loureiro <i>et al.</i> , 2015) ⁵⁹	Fair	na	na	Excellent	Fair	Fair	na	na
FCCHL-AYAC (McDonald <i>et al.</i> , 2016) ⁶⁰	Fair	na	na	Good	Fair	Fair	na	na

Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsive -ness
					Structural validity	Hypotheses testing	Cross-cultural validity	
ICHL (Smith <i>et al.</i> , 2016) ⁶¹	na	na	na	Good	na	Fair	na	na
HELMA (Ghanbari <i>et al.</i> , 2016) ⁶²	Good	Good	na	Good	Good	na	na	na
HLSAC (Paakkari <i>et al.</i> , 2016) ⁶³	Fair	Fair	na	Good	Fair	Fair	na	na
REALM-TeenS (Manganello <i>et al.</i> , 2017) ⁶⁴	Good	na	na	Good	na	Good	na	na
funHLS-YA (Tsubakita <i>et al.</i> , 2017) ⁶⁵	Fair	na	na	Poor	Fair	Fair	na	na
HLS-TCO (Intarakamhang <i>et al.</i> , 2017) ⁶⁶	Fair	na	na	Good	Fair	Fair	na	na
HLRS-Y (Bradley-Klug <i>et al.</i> , 2017) ⁶⁷	Fair	na	na	Excellent	Fair	Fair	na	na
p_HLAT-8 (Quemelo <i>et al.</i> , 2017) ⁶⁸	Fair	na	na	Good	Fair	Fair	Fair	na

Note: na, no information available. CHC Test, Critical Health Competence Test; CHLT, Child Health Literacy Test; c-sTOFHLA, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; funHLS-YA, Functional Health Literacy Scale for Young Adults; HAS-A, Health Literacy Assessment Scale for Adolescents; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, 8-item Health Literacy Assessment Tool; HLAT-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; VOHL, Visual Oral Health Literacy.

Table 4. Evaluation of measurement properties for included instruments according to Terwee's quality criteria

Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsiveness
					Structural validity	Hypotheses testing	Cross-cultural validity	
NVS (Hoffman <i>et al.</i> , 2013) ⁵⁰	-	na	na	?	na	-	na	na
NVS (Driessnack <i>et al.</i> , 2014) ⁵⁴	+	na	na	?	na	-	na	na
NVS (Warsh <i>et al.</i> , 2014) ³⁹	na	na	na	?	na	+	na	na
TOFHLA (Chisolm and Buchanan, 2007) ⁴⁸	na	na	na	?	na	-	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013) ⁵⁰	+	na	na	?	na	-	na	na
c-sTOFHLAd (Chang <i>et al.</i> , 2012) ⁵¹	+	+	na	+	?	+	?	na
REALM-Teen (Davis <i>et al.</i> , 2006) ⁴¹	+	+	na	+	na	+	na	na
REALM-Teen (Hoffman <i>et al.</i> , 2013) ⁵⁰	+	na	na	?	na	-	na	na
HLAB (Wu <i>et al.</i> , 2010) ⁴⁰	+	+	na	+	na	-	na	na
MMAHL (Massey <i>et al.</i> , 2013) ⁴⁴	+	na	na	+	-	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011) ⁴⁹	+	na	na	+	na	+	na	na
DNT-39 (Mulvaney <i>et al.</i> , 2013) ⁵³	+	na	na	?	na	-	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013) ⁵³	+	na	na	?	na	-	na	na
eHEALS (Norman and Skinner, 2006) ⁴³	+	-	na	+	+	-	na	na
CHC Test (Steckelberg <i>et al.</i> , 2009) ⁴⁷	na	+	na	+	+	na	na	na
HKACSS (Schmidt <i>et al.</i> , 2010) ⁴⁶	+(HC) - (HA)	na	na	+	na	+	na	na
HLAT-51 (Harper, 2014) ⁴²	?	na	na	+	?	na	na	na
HLAT-8 (Abel <i>et al.</i> , 2014) ⁴⁵	-	na	na	?	+	+	na	na
CHLT (Liu <i>et al.</i> , 2014) ⁵⁵	+	na	na	+	+	+	na	na
VOHL (Ueno <i>et al.</i> , 2014) ⁵⁶	na	-(TS) + (GS)	na	na	na	-	na	+
HAS-A (Manganello <i>et al.</i> 2015) ⁵⁷	+	na	na	+	+	-	na	na
MaHeLi (Naigaga <i>et al.</i> 2015) ⁵⁸	+	na	na	?	+	na	na	na
QuALiSMental (de Jesus Loureiro <i>et al.</i> , 2015) ⁵⁹	-	na	na	+	+	+	na	na
FCCHL-AYAC (McDonald <i>et al.</i> , 2016) ⁶⁰	+(FHL) - (IHL) +(CHL)	na	na	+	+	-	na	na
ICHL (Smith <i>et al.</i> , 2016) ⁶¹	na	na	na	+	na	+	na	na
HELMA (Ghanbari <i>et al.</i> , 2016) ⁶²	+	+	na	+	+	na	na	na
HLSAC (Paakkari <i>et al.</i> , 2016) ⁶³	+	+	na	+	-	+	na	na
REALM-TeenS (Manganello <i>et al.</i> ,	+	na	na	+	na	+	na	na

Health literacy instrument (Author, year)	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsiveness
					Structural validity	Hypotheses testing	Cross-cultural validity	
2017) ⁶⁴								
funHLS-YA (Tsubakita <i>et al.</i> , 2017) ⁶⁵	+	na	na	?	+	-	na	na
HLS-TCO (Intarakamhang <i>et al.</i> , 2017) ⁶⁶	+	na	na	+	+	+	na	na
HLRS-Y (Bradley-Klug <i>et al.</i> , 2017) ⁶⁷	+	na	na	+	+	+	na	na
p_HLAT-8 (Quemelo <i>et al.</i> , 2017) ⁶⁸	+	na	na	+	+	-	+	na

Note: na, no information available; + positive rating; ? indeterminate rating; - negative rating. CHC Test, Critical Health Competence Test; CHL, Critical Health Literacy; CHLT, Child Health Literacy Test; c-sTOFHLAd, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; FHL, Functional Health Literacy; funHLS-YA, Functional Health Literacy Scale for Young Adults; GS, Gingiva Score; HA, Health Attitude; HAS-A, Health Literacy Assessment Scale for Adolescents; HC, Health Communication; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, 8-item Health Literacy Assessment Tool; HLAT-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; IHL, Interactive Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; TS, Tooth Score; VOHL, Visual Oral Health Literacy.

Table 5. The overall quality of measurement properties for each health literacy instrument used in children and adolescents

Health instrument	literacy	Internal consistency	Reliability	Measurement error	Content validity	Construct validity			Responsive-ness
						Structural validity	Hypotheses testing	Cross-cultural validity	
NVS ^{50,54,39}		?	na	na	?	na	±	na	na
TOFHLA ⁴⁸		na	na	na	?	na	-	na	na
s-TOFHLA ⁵⁰		?	na	na	?	na	-	na	na
c-sTOFHLAd ⁵¹		+	+	na	++	?	+	?	na
REALM-Teen ^{41,50}		?	+	na	++	na	+	na	na
HLAB ⁴⁰		+	?	na	++	na	-	na	na
MMAHL ⁴⁴		++	na	na	++	--	na	na	na
MHL ⁴⁹		?	na	na	++	na	++	na	na
DNT-39 ⁵³		+	na	na	?	na	-	na	na
DNT-14 ⁵³		+	na	na	?	na	-	na	na
eHEALS ⁴³		+	-	na	++	+	-	na	na
CHC Test ⁴⁷		na	?	na	++	?	na	na	na
HKACSS ⁴⁶		+++ (HC) --- (HA)	na	na	++	na	++	na	na
HLAT-51 ⁴²		?	na	na	++	?	na	na	na
HLAT-8 ⁴⁵		---	na	na	?	+++	++	na	na
CHLT ⁵⁵		+	na	na	++	+	+	na	na
VOHL ⁵⁶		na	- (TS) + (GS)	na	na	na	-	na	+
HAS-A ⁵⁷		+	na	na	++	+	-	na	na
MaHeLi ⁵⁸		+	na	na	?	+	na	na	na
QuALiSMental ⁵⁹		-	na	na	+++	+	+	na	na
FCCHL-AYAC ⁶⁰		+(FHL) -(IHL) +(CHL)	na	na	++	+	-	na	na
ICHL ⁶¹		na	na	na	++	na	+	na	na
HELMA ⁶²		++	++	na	++	++	na	na	na
HLSAC ⁶³		+	+	na	++	-	+	na	na
REALM-TeenS ⁶⁴		++	na	na	++	na	++	na	na
funHLS-YA ⁶⁵		+	na	na	?	+	-	na	na
HLS-TCO ⁶⁶		+	na	na	++	+	+	na	na
HLRS-Y ⁶⁷		+	na	na	+++	+	+	na	na
p_HLAT-8 ⁶⁸		+	na	na	++	+	-	+	na

Note: na, no information available; +++ or --- strong evidence and positive/negative result; ++ or -- moderate evidence and positive/negative result; + or - limited evidence and positive/negative

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result; ± conflicting evidence; ? unknown, due to poor methodological quality or indeterminate rating of a measurement property. CHC Test, Critical Health Competence Test; CHL, Critical Health Literacy; CHLT, Child Health Literacy Test; c-STOFHLAd, Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, Diabetes Numeracy Test; eHEALS, eHealth Literacy Scale; FCCHL-AYAC, Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; FHL, Functional Health Literacy; funHLS-YA, Functional Health Literacy Scale for Young Adults; GS, Gingiva Score; HA, Health Attitude; HAS-A, Health Literacy Assessment Scale for Adolescents; HC, Health Communication; HELMA, Health Literacy Measure for Adolescents; HKACSS, Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAB-8, 8-item Health Literacy Assessment Tool; HLAB-51, 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; IHL, Interactive Health Literacy; MaHeLi, Maternal Health Literacy; MHL, Media Health Literacy; MMAHL, Multidimensional Measure of Adolescent Health Literacy; NVS, Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, Rapid Estimate of Adolescent Literacy in Medicine Short Form; s-TOFHLA, short-form Test of Functional Health Literacy in Adults; TOFHLA, Test of Functional Health Literacy in Adults; TS, Tooth Score; VOHL, Visual Oral Health Literacy.

Peer review only

Discussion

Summary of main results

This study identified and examined 29 health literacy instruments used in children and adolescents and exemplified the large variety of methods used. Compared to previous three systematic reviews,^{10 11 13} this review identified 19 additional new health literacy instruments and critically appraise measurement properties of each instrument. It showed that to date, only half of included health literacy instruments (15/29) measure all three domains (functional, interactive and critical) and that the functional domain is still the focus of attention when measuring health literacy in children and adolescents. Additionally, researchers mainly focus on participant characteristics of developmental change (of cognitive ability), dependency (on parents) and demographic patterns (e.g. racial/ethnic backgrounds), and less so on differential epidemiology (of health and illness). The methodological quality of included studies as assessed via measurement properties varied from poor to excellent. Most information (62.9%) on measurement properties was unknown due to either the poor methodological quality of studies or a lack of reporting or assessment. It is therefore difficult to draw a robust conclusion about which instrument is the best.

Health literacy measurement in children and adolescents

This review found that health literacy measurement in children and adolescents tends to include Nutbeam's three-domain health literacy construct (i.e. functional, interactive and critical), especially in the past five years. However, almost one third of included instruments focused only on the functional domain (n=10). Unlike health literacy research for patients in clinics, health literacy research for children and adolescents (a comparatively healthy population) should be considered from a health promotion perspective,⁶⁹ rather than a health care or disease management perspective. Integrating interactive and critical domains into health literacy measurement is aligned with the rationale of emphasising empowerment in health promotion for children and adolescents.⁷⁰ The focus of health literacy for this population group

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3 should therefore include all three domains and so there is a need for future research to
4 integrate the three domains within health literacy instruments.
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8 Similar to previous findings by Ormshaw *et al.*¹⁰ and Okan *et al.*,¹³ this review also
9 revealed that childhood and adolescent health literacy measurement varied by its
10 dimensions, health topics, forms of administration, and by the level to which
11 participant characteristics were considered. There are likely four main reasons for
12 these disparities. First, definitions of health literacy were inconsistent. Some
13 researchers measured general health literacy,^{40 45} while others measured eHealth
14 literacy or media health literacy.^{43 49} Second, researchers had different research
15 purposes for their studies. Some researchers used what were originally adult
16 instruments to measure adolescent health literacy,^{39 48 52} whereas others developed
17 new or adapted instruments.^{40-42 53} Third, the research settings affected the
18 measurement process. As clinical settings were busy, short surveys were more
19 appropriate than long surveys.^{39 41 44} On the other hand, health literacy in school
20 settings was often measured using long and comprehensive surveys.^{40 42 47} Fourth,
21 researchers considered different participant characteristics when measuring health
22 literacy in children and adolescents. For example, some researchers took
23 considerations of students' cognitive development,^{40 41 44 46 51} some focused on
24 adolescents' resources and environments (e.g. friends and family contexts, eHealth
25 contexts, media contexts),^{43 45 49} and others looked at the effect of different cultural
26 backgrounds and socio-economic status.^{40 41 43 44 46 47 49-52} Based on Forrest *et al.*'s 4D
27 model,^{14 15} this review showed that most health literacy instruments considered
28 participants' development, dependency and demographic patterns, with only seven
29 instruments considering differential epidemiology.^{53 58 60 61 66 67} Although the '4D'
30 model cannot be used to reduce the disparities in health literacy measurement, it does
31 provide an opportunity to identify gaps in current research and assist researchers to
32 consider participants' characteristics comprehensively in future research.
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49 **The methodological quality of included studies**

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52 This review included a methodological quality assessment of included studies, which
53 was absent from previous reviews on this subject.^{10 11} Methodological quality
54 assessment is important because strong conclusions about the measurement properties
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of instruments can only be drawn from high-quality studies. In this review, the COSMIN checklist was shown to be a useful framework for critically appraising the methodological quality of studies via each measurement property. Findings suggested that there was wide variation in the methodological quality of studies for all instruments. Poor methodological quality of studies was often seen in the original or adapted health literacy instruments (the NVS, the TOFHLA, the s-TOFHLA, the DNT-39 and the DNT-14) for two main reasons. The first reason was the vague description of the target population involved. This suggested that researchers were less likely to consider an instrument's content validity when using the original, adult instrument for children and/or adolescents. Given that children and adolescents have less well-developed cognitive abilities, in future it is essential to assess whether all items within an instrument are understood. The second reason was a lack of unidimensionality analysis for internal consistency. As explained by the COSMIN group,⁷¹ a set of items can be inter-related and multi-dimensional, whereas unidimensionality is a prerequisite for a clear interpretation of the internal consistency statistics (Cronbach's alpha). Future research on the use of health literacy instruments therefore needs to assess and report both internal consistency statistics and unidimensionality analysis (e.g. factor analysis).

Critical appraisal of measurement properties for included instruments

This review demonstrated that of all instruments reviewed three instruments (the c-TOFHLAd, the HELMA and the HLSAC) showed satisfactory evidence about internal consistency and test-retest reliability. Based on the synthesised evidence, the HELMA showed moderate evidence and positive results of internal consistency ($\alpha=0.93$) and test-retest reliability (intraclass correlation coefficient (ICC)=0.93), whereas the HLSAC ($\alpha=0.93$; standardised stability estimate=0.83) and the c-TOFHLAd ($\alpha=0.85$; ICC=0.95) showed limited evidence and positive results. Interestingly, compared to the overall reliability rating of the s-TOFHLA,⁵⁰ the c-TOFHLAd showed better results.⁷² The reason for this was probably the different methodological quality of the studies that examined the s-TOFHLA and the c-TOFHLAd. The c-TOFHLAd study had fair methodological quality in terms of

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3 internal consistency and test-retest reliability, whereas the original s-TOFHLA study
4 had poor methodological quality for internal consistency and unknown information
5 for test-retest reliability. Given the large disparity of rating results between the
6 original and translated instrument, further evidence is needed to confirm whether the
7 s-TOFHLA has the same or a different reliability within different cultures, thus
8 assisting researchers to understand the generalisability of the s-TOFHLA's reliability
9 results.
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16 Four instruments were found to show satisfactory evidence about both content
17 validity and construct validity (structural validity and hypotheses testing). Construct
18 validity is a fundamental aspect of psychometrics and was examined in this review for
19 two reasons. First, it enables an instrument to be assessed for the extent to which
20 operational variables adequately represent underlying theoretical constructs.⁷³ Second,
21 the overall rating results of content validity for all included instruments were similar
22 (i.e. unknown or moderate/strong evidence and positive result). The only difference
23 was that the target population was involved or not. Given that all instruments' items
24 reflected the measured construct, in this review, construct validity was determined to
25 be key to examining the overall validity of included instruments. In this context, only
26 the HLAT-8 showed strong evidence and positive result for structural validity
27 (CFI=0.99; TLI=0.97; RMSEA=0.03; SRMR=0.03) and moderate evidence on
28 hypotheses testing (known-group validity results showed differences of health literacy
29 by gender, educational status and health valuation). However, in the original paper,⁴⁵
30 the HLAT-8 was only tested for its known-group validity, not for convergent validity.
31 Examination of convergent validity is important because it assists researchers in
32 understanding the extent to which two examined measures' constructs are
33 theoretically and practically related.⁷⁴ Therefore, future research on the convergent
34 validity of the HLAT-8 would be beneficial for complementing that which exists for
35 its construct validity.
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49 Similar to a previous study by Jordan *et al.*,²⁶ this review demonstrated that only one
50 included study contained evidence of responsiveness. Ueno *et al.*⁵⁶ developed a visual
51 oral health literacy instrument and examined responsiveness by comparing changes in
52 health literacy before and after oral health education. Their results showed students'
53 health literacy scores increased significantly after health education. Responsiveness is
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3 the ability of an instrument to detect change over time in the construct being measured,
4 and it is particularly important for longitudinal studies.³¹ However, most studies
5 included in this review were cross-sectional studies, and only one study (on the
6 MMAHL⁴⁴) discussed the potential to measure health literacy over time. Studies that
7 measure health literacy over time in populations are needed, not only because this is a
8 prerequisite for longitudinal studies, but also so that the responsiveness of instruments
9 can be monitored and improved.
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15 **Feasibility issues for included instruments**

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18 This review showed that the feasibility aspects of instruments varied markedly. In
19 relation to forms of administration, this review identified 19 self-administered
20 instruments and 10 interviewer-administered instruments. This suggests that self-
21 administered instruments are more commonly used in practice than interviewer-
22 administered instruments. However, both administration modes have limitations. Self-
23 administered instruments are cost-effective and efficient, but may bring about
24 respondent bias, whereas interviewer-administered instruments, while able to ensure
25 high response rates, are always resource intensive and expensive to administer.⁷⁵
26 Although the literature showed that there was no significant difference in scores
27 outcome between these two administration modes,^{76 77} the relevant studies mostly
28 concerned health-related quality of life instruments. It is still unknown whether the
29 same is true for health literacy instruments. Among children and adolescents, health
30 literacy research is more likely to be conducted through large-scale surveys in school
31 settings. Therefore, the more cost-effective, self-administered mode seems to have
32 great potential for future research. To further support the wide use of self-
33 administered instruments, there is a need for future research to confirm the same
34 effect of administration between self-administered and interviewer-administered
35 instruments.
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50 With regard to the type of assessment method, this review revealed that performance-
51 based health literacy instruments (n=15) are more preferable than self-report
52 instruments (n=11). There might be two reasons for this. First, it is due to participant
53 characteristics. Compared with adults, children and adolescents are more dependent
54 on their parents for health-related decisions.¹⁵ Measurement error is more likely to
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3 occur when children and adolescents answer self-report items.⁷⁸ Therefore,
4 performance-based assessment is often selected to avoid such inaccuracy. Second,
5 performance-based instruments are objective, whereas self-report instruments are
6 subjective and may bring about over-estimated results.⁷⁹ However, the frequent use of
7 performance-based instruments does not mean that they are more appropriate than
8 self-report instruments when measuring childhood and adolescent health literacy.
9 Compared with performance-based instruments, self-report instruments are always
10 time-efficient and help to preserve respondents' dignity.²¹ The challenge in using self-
11 report instruments is to consider the readability of tested materials. If children and
12 adolescents can understand what a health literacy instrument measures, then they are
13 more able to accurately self-assess their own health literacy skills.⁷⁰ The difference
14 between self-report and performance-based instruments of health literacy has been
15 discussed in the literature,⁸⁰ but the evidence about the difference is still limited due
16 to a lack of specifically-designed studies for exploring the difference. Further studies
17 are needed to fill this knowledge gap.

28 **Recommendations for future research**

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32 This review identified 18 instruments (the REALM-Teen, the NVS, the s-TOFHLA,
33 the c-sTOFHLAd, the eHEALS, the CHC Test, the HKACSS, the HLAB, the MHL,
34 the HLAT-51, the CHLT, the VOHL, the QuALiSMental, the HELMA, the HLSAC,
35 the funHLS-YA, the HLS-TCO and the p_HLAT-8) that were used to measure health
36 literacy in school settings. Although it is difficult to categorically state which
37 instrument is the best, this review provides useful information that will assist
38 researchers to identify the most suitable instrument to use when measuring health
39 literacy in children and adolescents in school contexts.

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46 Among the 18 instruments, six tested functional health literacy (the REALM-Teen,
47 the NVS, the s-TOFHLA, the c-sTOFHLAd, the VOHL and the funHLS-YA); one
48 examined critical health literacy (the CHC Test); one measured functional and
49 interactive health literacy (the HKACSS); one examined functional and critical health
50 literacy (the HLAB); and nine tested health literacy comprehensively focusing on
51 functional, interactive and critical domains (the eHEALS, the MHL, the HLAT-51,
52 the CHLT, the QuALiSMental, the HELMA, the HLSAC, the HLS-TCO and the
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p_HLAT-8). However, only one of these three-domain instruments (the HLSAC) was considered appropriate for use in schools because of its quick administration, satisfactory reliability and one-factor validity. Eight three-domain instruments were excluded due to the fact that they focused on non-general health literacy (the eHEALS, the MHL, the QuALiSMental, the HLS-TCO) or were burdensome to administer (the HLAT-51, the HELMA-44) or were not published in English (the CHLT and the p_HLAT-8).

Compared with the HLSAC, the HLAT-8 examines the construct of health literacy via three domains rather than one-factor structure, thus enabling a more comprehensive examination of the construct. Meanwhile, although the p_HLAT-8 (Portuguese version) is not available in English, the original HLAT-8 is. After comparing measurement domains and measurement properties, the HLAT-8 was deemed to be more suitable for measuring health literacy in school settings for four reasons: (1) it measures health literacy in the context of family and friends,⁴⁵ a highly important attribute because children and adolescents often need support for health decisions from parents and peers;^{7 15} (2) it is a short but comprehensive tool that captures Nutbeam's three-domain nature of health literacy;¹⁷ (3) it showed satisfactory structural validity (RMSEA=0.03; CFI=0.99; TLI=0.97; SRMR=0.03);⁴⁵ and (4) it has good feasibility (e.g. the p_HLAT-8 is self-administered and time-efficient) in school-based studies. However, there are still two main aspects that need to be considered in future. One aspect is its use in the target population. Given the HLAT-8 has not been tested for children and adolescents under 18, its readability and measurement properties need to be evaluated. The other aspect is that its convergent validity (the strength of association between two measures of a similar construct, an essential part of construct validity) has not been examined. Testing convergent validity of the HLAT-8 is important because high convergent validity assists researchers to understand the extent to which two examined measures' constructs are theoretically and practically related.

Limitations

This review was not without limitation. First, we restricted the search to studies aiming to develop or validate a health literacy instrument. Thus we may have missed

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3 relevant instruments in studies that were not aiming to develop instruments.^{81 82}
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5 Second, although the COSMIN checklist provided us with strong evidence of the
6
7 methodological quality of a study via an assessment of each measurement property, it
8
9 cannot evaluate a study's overall methodological quality. Third, criterion validity was
10
11 not examined due to lack of 'gold standard' for health literacy measurement. However,
12
13 we examined convergent validity under the domain of 'hypotheses testing'. This can
14
15 ascertain the validity of newly-developed instruments against existing commonly-
16
17 used instruments. Finally, individual subjectivity inevitably played a part in the
18
19 screening, data extraction and synthesis stage of the review. To reduce this
20
21 subjectivity, two authors independently managed the major stages.

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CONCLUSION

This review updated previous reviews of childhood and adolescent health literacy measurement (c.f. Ormshaw *et al.*, Perry & Okan *et al.*) to incorporate a quality assessment framework. It showed that most information on measurement properties was unknown due to either the poor methodological quality of studies or a lack of assessment and reporting. Rigorous and high-quality studies are needed to fill the knowledge gap in relation to health literacy measurement in children and adolescents. Although it is challenging to draw a robust conclusion about which instrument is the best, this review provides important evidence that supports the use of the HLAT-8 to measure childhood and adolescent health literacy in future research.

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CONTRIBUTORS

1
2
3 SG conceived the review approach. RA and EW provided general guidance for the
4 drafting of the protocol. SG and SA screened the literature. SG and TS extracted data.
5 SG drafted the manuscript. SG, GB, RA, EW, XY, SA and TS reviewed and revised
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18 19 **COMPETING INTERESTS**

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22 None.
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25 26 **DATA SHARING STATEMENT**

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28
29 There are no additional data available.
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32 33 **REFERENCES**

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FIGURE

Figure 1. Flowchart of search and selection process according to PRISMA flow diagram

For peer review only

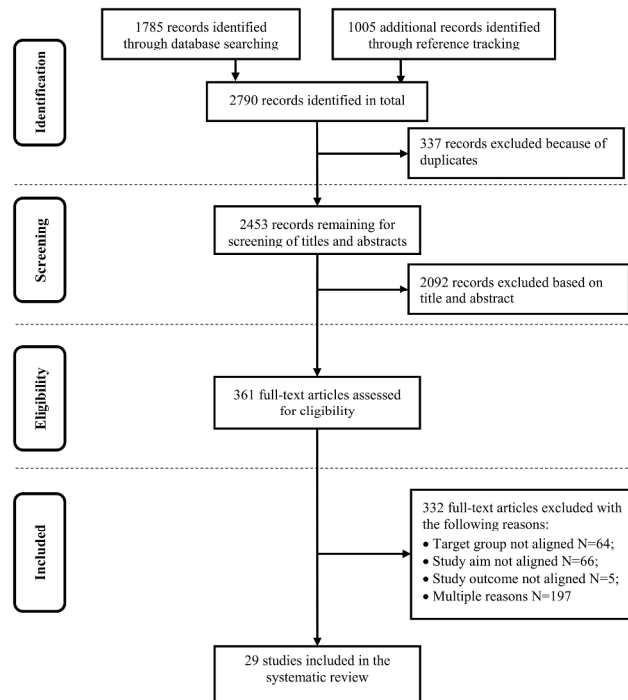


Figure 1. Flowchart of search and selection process according to PRISMA flow diagram

297x420mm (300 x 300 DPI)

Appendix 1. A systematic review protocol

Measuring the Quality of Child and Adolescent Health Literacy Instruments: A Systematic Review

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Background

Health literacy research has been a growing interest by researchers across the globe. The term 'health literacy' was first used in 1974 in the proceedings of a health education conference discussing health education as a social policy issue affecting the healthcare system, mass communication and the education system (1, 2). However, few references were found regarding health literacy in the literature until 1992 (3). Since 1992, health literacy has been broadly studied both in clinical and public health contexts. In clinical settings, health literacy is typically defined as 'the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions' by the Institute of Medicine (IOM) in America (4). In such circumstances, health literacy is a derivative concept from literacy and numeracy skills, which is often used as a risk factor that needs to be identified and appropriately managed for patients and health professionals (5). Accordingly, health literacy measurement tools and 'screening aids' for clinicians are developed to assess patient literacy levels, and help health professionals to tailor health information for better communication with their patients (6). From the public health perspective, health literacy is defined and accepted by World Health Organization (WHO) as 'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health' (7). This understanding of health literacy identifies it as a broad concept, which is seen as a personal asset to enable individuals to take more control over their health and determinants of health (5). With a different understanding of the concept, health literacy measures vary in a different way. Although health literacy measurement varies and is still

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3 being debated (1, 8-10), there is consistent evidence showing health literacy is of potential
4 importance and considered as a public health goal internationally. A recent WHO report
5 pointed out that poor health literacy skills were associated with riskier behaviours, poorer
6 health status, less self-management and longer hospitalization and more health costs (11).
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11 Based on a preliminary search of health literacy, there were more interests in studies focusing
12 on adult health literacy than adolescent health literacy. However, previous research studies
13 suggested that poor health literacy was a prevalent problem in adolescents. In Australia, the
14 2006 National Health Literacy Survey reported that 67.6% of adolescents aged 15 to 19 years
15 old did not attain the minimum skills required to deal with health information and service in
16 everyday life (12). Compared with adult health literacy, there are several reasons for the
17 potential importance of adolescent health literacy: 1) adolescents are future mainstream and
18 independent healthcare consumers, a health literate person can contribute to less health care
19 costs, better health status compared to that is not health literate (13); 2) adolescents are at a
20 critical stage of development characterised by physical, emotional and cognitive changes,
21 attempting to prepare for independence but lacking the adequate ability of reasoning and
22 decision-making. Therefore, improving their health literacy skills could support sound health
23 decisions in future (14, 15); 3) low health literacy has been demonstrated to associate with
24 high levels of health-risk behaviors (16, 17) and low levels of health-promoting behaviors for
25 adolescents (18); 4) enhancing health literacy through school-based interventions has great
26 potential for improving students' access to and interpretation of health information (19).
27 Adolescents spend most of their daily time in school, which means they can receive health
28 education and learn how to improve healthy lifestyles and related skills through this setting
29 (20, 21).
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42 Health literacy is more challenging to understand for adolescents than that for adults.
43 Researchers may have different understandings and underlying constructs when using the
44 same definition. That is why there are such a large number of measurement tools of health
45 literacy currently (22, 23), along with some newly-developed health literacy instruments (24).
46 According to Mancuso (1), it is recommended to use specific assessment tools for a specific
47 age group in a specific context. Studies measuring childhood and adolescent health literacy
48 have been a research focus, particularly in the past five years (23). Ormshaw *et al.* (23)
49 conducted a systematic review on measuring childhood and adolescent health literacy in
50 2011. They found 16 studies that were involved with health literacy measures in children and
51 adolescents. The authors also identified 13 health topics and nine underlying components
52 from existing health literacy instruments. However, the authors did not critically appraise
53 health literacy indices explicitly regarding their validity and reliability. More importantly, the
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3 authors did not assess the methodological quality of each included study. This may undermine
4 the persuasiveness of its conclusion. To fill this knowledge gap, we aim to conduct a
5 systematic review that examines studies' methodological quality and examine reliability and
6 validity of each health literacy instrument, thus providing researchers with unbiased
7 information about which instruments have good psychometric properties. The '*CO*
8 *nsensus-based Standards for the selection of health status Measurement INstruments*' (COSMIN)
9 group has recently developed as a critical appraisal tool (a checklist) to evaluate the
10 methodological quality of studies on measurement properties of health measurement
11 instruments (25). These measurement properties are divided into three domains: reliability,
12 validity, and responsiveness (26). According to the COSMIN checklist, it is possible and
13 scientific to critically appraise and compare psychometric properties of health literacy
14 instruments for children and adolescents.

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16 In this protocol, our target population is adolescent. According to the definition of the WHO,
17 adolescents are those people aged 10 to 19 years and young people aged 10-24 years (27, 28).
18 Given that the term '*adolescent*', '*child*', '*youth*' and '*young people*' is closely related, and
19 Erikson (29) reckoned that children between the ages of 6 and 12 years could learn, compete
20 and co-operate with others, we define our target group as those aged 6-24 years old.

21 22 23 24 25 26 27 28 29 30 31 32 33 **Objectives of the review**

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36 This review aims to identify which health literacy instruments have good psychometric
37 properties for children and adolescents. Specifically, there are three objectives:

- 38 1) To examine the methodological quality of included studies that aim to measure
39 health literacy in children and adolescents;
- 40 2) To examine the measurement properties (i.e. reliability; validity; responsiveness)
41 of health literacy instruments in children and adolescents;
- 42 3) To compare the overall rating of measurement properties between each health
43 literacy instrument used in children and adolescents.

44 45 46 47 48 49 50 51 **Search strategy**

52 53 54 **Database and search terms**

55 As the term '*health literacy*' was first coined in 1974, articles published from 1st,January
56 1974 to 30th May 2014 in all languages will be searched. Search strategies will be first
57 designed and then be consulted with two librarian experts. Articles indexed in the following
58 seven databases: Medline, Pubmed, Embase, PsycINFO, CINAHL, ERIC and Cochrane
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Library will be searched. The search key terms are ‘*health literacy*’ and ‘*assessment*’ according to previously published studies (1, 23, 30, 31). Age group for ‘*child, adolescent and young adult*’ will be defined in the database settings. The synonyms are listed in **Appendix Table 1**. These synonyms are connected by ‘*or*’ and search strategies are completed by ‘*and*’.

Appendix Table 1 Searching terms in databases

Key term (1)	Key term (2)
health literacy	health literacy measur*
health AND literacy AND education	health literacy assess*
	health literacy evaluat*
	health literacy instrument*
	health literacy tool*

Other sources of literature

Searching other sources to identify relevant research including:

- Reference lists of identified studies;
- Reference lists of previous systematic reviews on health literacy (1, 23, 30-33).

Eligibility criteria for inclusion and exclusion

According to the guidelines recommended by Cochrane Handbook for systematic reviews (34), inclusion criteria will be addressed regarding population, intervention, comparison, outcome and study design (PICOS):

Inclusion criteria-Participants

The target group should be children and/or adolescents, any age from 6 to 24 years of age.

Inclusion criteria-Interventions and Comparators

As interventional studies are not our interest in this review, it is not applicable to set out guidelines for interventions and comparators

Inclusion criteria-Outcomes

The included studies must be involved with health literacy assessment for children and adolescents, that is, the study should specify the term ‘*health literacy*’, and studies are included if they report on at least one or more attributes of the three measurement properties: 1) reliability; 2) validity; and 3) responsiveness.

Inclusion criteria-Study design

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3 The article should be research-based and peer-reviewed paper including study aim, methods,
4 and results. Also, the study aim should focus on health literacy instrument development or
5 validation.
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9 ***Exclusion criteria***

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11 Studies will be excluded if they are: 1) not focusing on the target group; 2) not focusing on
12 the health literacy instrument development or tool validation; 3) not research-based and peer-
13 reviewed papers including editorials, comments and letters; 4) not reporting findings or
14 results regarding any one of the measurement properties.
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18 **Study selection**

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22 Search records will be kept including the names of databases searched, keywords, search
23 timeframe, and the search results. All the electronic search results will be initially inputted
24 into the bibliography software of EndNote X7 (Thomson Reuters, New York, NY), and other
25 sources of literature results will be summarised in the print paper. This screening process will
26 follow the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)
27 statement (35). One reviewer will screen studies by titles and abstracts. Secondly, full copies
28 of articles identified will be obtained for thorough screening according to the inclusion
29 criteria by two reviewers independently. Any disagreements in reviewer selections will be
30 resolved at a meeting.
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38 **Quality assessment**

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41 The methodological quality of each included study will be assessed by two reviewers
42 independently using the COSMIN checklist (25). The checklist consists of nine boxes with 5-
43 18 items concerning methodological standards for how each measurement property should be
44 assessed. Four response options for each item of the COSMIN checklist are defined,
45 representing 'excellent', 'good', 'fair' and 'poor' quality. An overall score for the
46 methodological quality of a study will be determined for each measurement property
47 separately, by taking the lowest rating of any items in a box ('worst score counts') (36).
48 Discrepancies arise between the reviewers will be resolved through discussion, if necessary
49 with a third independent person.
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57 **Data extraction**

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59 Data extraction will be performed along with the assessment of methodological quality using
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3 the COSMIN checklist (25). In addition, information on the interpretability (e.g. norm scores,
4 floor-ceiling effects, minimal important change of the instruments), generalisability (e.g.
5 characteristics of the study population and sampling procedure), respondent and
6 administrative burden, and forms of administration will be also collected because they are
7 important characteristics of a measurement instrument (26, 37). The data will be entered in an
8 electronic form. Where possible, authors of the original studies will be contacted to obtain
9 essential missing or additional data. Two reviewers will independently extract the data.
10 Consensus should be reached afterward, if necessary with a third independent person.
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17 Data synthesis

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20 The results of the quality of health literacy instruments will be assessed using Terwee's
21 quality criteria (38), to see whether the results of the measurement attributes are 'positive',
22 'negative', or 'indeterminate'. To summarise the overall ratings of the measurement
23 properties of one health literacy instruments by different authors, the synthesis will be
24 performed by combining the results of the quality of health literacy instruments, the results of
25 methodological quality of health literacy measurement studies and the consistency of their
26 results. The possible overall rating for a measurement property is 'positive', 'indeterminate',
27 or 'negative', accompanied by levels of evidence, similarly as was proposed by the Cochrane
28 Back Review Group (39, 40). One reviewer will perform the data synthesis and a second
29 reviewer will check the synthesised results. Discrepancies of the results will be resolved by
30 discussion.
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For peer review only

Appendix 2. Search strategy for seven databases

This section has two parts for SEARCH STRATEGY. The first part focuses on the timeline of 1974 to 2014. The second part focuses on the timeline of May 2014 to Jan 2018.

Part 1:

1 MEDLINE (Web of Science) search strategy

MEDLINE database was searched using the Web of Science interface on 16/05/2014 for the period 1974 to 2014.

Basic search:

Set	Results	
# 1	<u>500</u>	MeSH HEADING: (health literacy) OR ((TITLE: (health literacy) OR MeSH HEADING:exp: (Health Literacy)) AND (TITLE: (education) OR MeSH HEADING:exp: (Educational Status) OR MeSH HEADINGS:exp: (/education) OR MeSH HEADING:exp: (Teaching) OR MeSH HEADING:exp: (Educational Status) OR MeSH HEADING:exp: (Education))) Refined by: MeSH HEADINGS: (ADOLESCENT OR YOUNG ADULT OR CHILD) Indexes=MEDLINE Timespan=1974-2014
# 2	<u>3,880</u>	TOPIC: (((health) literacy assess* OR health literacy measur*) OR health literacy evaluat*) OR health literacy instrument*) OR health literacy tool*) Indexes=MEDLINE Timespan=1974-2014
# 3	<u>352</u>	#2 AND #1 Indexes=MEDLINE Timespan=1974-2014

2 PubMed search strategy

PubMed database was searched (Advanced search) on 16/05/2014 for the period 1974 to 16/05/2014.

Set	Results	
# 1	<u>4910</u>	Search (health literacy[MeSH Terms]) OR (health AND education AND literacy[Title/Abstract]) Sort by: PublicationDate
# 2	<u>3248385</u>	Search (child* OR adolescent* OR student* OR youth OR young people OR teen* OR young adult[Title/Abstract]) Sort by: PublicationDate Because if we select age group including child, adolescent, and young adult, the newest papers such as published in 2014 will not be included, the reason maybe the database doesn't update properly. So we use these terms to identify.
# 3	<u>1887</u>	Search (health literacy assess* OR health literacy measur* OR health literacy evaluat* OR health literacy instrument* OR health literacy tool*) Sort by: PublicationDate
# 4	<u>581</u>	Search (((health literacy[MeSH Terms]) OR (health AND education AND literacy[Title/Abstract]))) AND ((health literacy assess* OR health literacy measur* OR health literacy evaluat* OR health literacy instrument* OR health literacy tool*)) AND ((child* OR adolescent* OR student* OR youth OR young people OR teen* OR young adult[Title/Abstract])) Filters: Publication date from 1974/01/01 to 2014/05/16 Sort by: PublicationDate

3 EMBASE (Ovid) search strategy

EMBASE database was searched using Ovid interface on 16/05/2014 for the period 1974 to current.

Using .mp as searching terms (Advanced Search):

Set	Results	
#1	<u>6060</u>	("health literacy" or (health and literacy and education)).mp.
#2	<u>6043</u>	limit 1 to yr="1974 -Current"
#3	<u>671</u>	limit 2 to (school child <7 to 12 years> or adolescent <13 to 17 years>)
#4	<u>170</u>	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*).mp.
#5	<u>170</u>	limit 4 to yr="1974 -Current"
#6	<u>18</u>	3 and 5

4 PsycINFO (EBSCO) search strategy

PsycINFO database was searched using EBSCO interface on 16/05/2014 for the period January 1974 to May 2014.

Advanced Search:

Set	Results		
#1	<u>786</u>	health literacy OR (health AND literacy AND education)	Limiters - Published Date: 19740101-20140531; Age Groups: School Age (6-12 yrs), Adolescence (13-17 yrs), Young Adulthood (18-29 yrs) Search modes - Boolean/Phrase
#2	<u>133</u>	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Published Date: 19740101-20140531; Age Groups: School Age (6-12 yrs), Adolescence (13-17 yrs), Young Adulthood (18-29 yrs) Search modes - Boolean/Phrase
#3	<u>133</u>	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*) AND (S1 AND S2)	Search modes - Boolean/Phrase

5 CINAHL (EBSCO) search strategy

CINAHL database was searched using EBSCO interface on 16/05/2014 for the period January 1974 to May 2014.

Advanced Search:

Set	Results		
#1	<u>437</u>	health literacy OR (health AND education AND literacy)	Limiters - Published Date: 19740101-20140531; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase
#2	<u>63</u>	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Published Date: 19740101-20140531; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase
#3	<u>63</u>	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*) AND (S1 AND S2)	Search modes - Boolean/Phrase

6 ERIC (EBSCO) search strategy

ERIC database was searched using EBSCO interface on 16/05/2014 for the period January 1974 to May 2014.

Advanced Search:

Set	Results		
#1	<u>59</u>	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Date Published: 19740101-20140531 Search modes - Boolean/Phrase
#2	<u>2,250</u>	health literacy OR (health AND education AND literacy)	Limiters - Date Published: 19740101-20140531 Search modes - Boolean/Phrase
#3	<u>59</u>	S1 AND S2	Search modes - Boolean/Phrase

7 The Cochrane Library search strategy

The Cochrane Library database was searched on 30/05/2014 for the period January 1974 to May 2014.

Set	Results	Sub-database
#1	<u>4</u>	Cochrane Reviews: There are 4 results from 8483 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Date from 1974 to 2014 in Cochrane Reviews'
#2	<u>114</u>	Trials: There are 114 results from 789657 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Date from 1974 to 2014 in Trials'
#3	<u>2</u>	Methods Studies: There are 2 results from 15764 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Date from 1974 to 2014 in Methods Studies'
#4	<u>120</u>	

PART 2:

The above seven databases were searched using similar rationale as describe before for the timeframe of May 17 2014 to Jan 31 2018.

MEDLINE was searched using the Web of Science interface on 17/02/2018 for the period 2014 to 2018.

Basic search:

Set	Results	
# 5	<u>35</u>	#4 AND #3 Indexes=MEDLINE Timespan=2014-2018
# 4	<u>14,198</u>	MeSH MAJOR TOPIC:exp: ((((((child*) OR adolescent*) OR student*) OR youth) OR young people) OR teen*) OR young adult) Indexes=MEDLINE Timespan=2014-2018
# 3	<u>1,779</u>	#2 AND #1 Indexes=MEDLINE Timespan=2014-2018
# 2	<u>3,482</u>	(((TOPIC: (health literacy assess*) OR TOPIC: (health literacy measur*) OR TOPIC: (health literacy instrument*) OR TOPIC: (health literacy tool*) OR TOPIC: (health literacy evaluat*)) Indexes=MEDLINE Timespan=2014-2018
# 1	<u>2,654</u>	((MeSH HEADING:exp: (health literacy) OR MeSH MAJOR TOPIC:exp: (health literacy)) OR TITLE: (health literacy)) OR MeSH MAJOR TOPIC: ((health) AND education) AND literacy Indexes=MEDLINE Timespan=2014-2018

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4 **Pubmed** was searched (Advanced search) on 17/02/2018 for the period 2014 to
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6 31/01/2018.
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Set	Results	
#6	<u>26</u>	Search (((((((health literacy[MeSH Terms]) OR health literacy[Title/Abstract]) OR (health[Title/Abstract] AND education[Title/Abstract] AND literacy[Title/Abstract])) OR (health[Title/Abstract] AND education[Title/Abstract] AND numeracy[Title/Abstract])) AND ((health literacy assess*[Title/Abstract] OR health literacy measur*[Title/Abstract] OR health literacy evaluat*[Title/Abstract] OR health literacy instrument*[Title/Abstract] OR health literacy tool*[Title/Abstract]))) AND ((child*[Title/Abstract] OR adolescent*[Title/Abstract] OR student*[Title/Abstract] OR youth[Title/Abstract] OR young people[Title/Abstract] OR teen*[Title/Abstract] OR young adult[Title/Abstract])) Filters:Publication date from 2014/05/16 to 2018/01/31
#5	<u>48</u>	Search (((((((health literacy[MeSH Terms]) OR health literacy[Title/Abstract]) OR (health[Title/Abstract] AND education[Title/Abstract] AND literacy[Title/Abstract])) OR (health[Title/Abstract] AND education[Title/Abstract] AND numeracy[Title/Abstract])) AND ((health literacy assess*[Title/Abstract] OR health literacy measur*[Title/Abstract] OR health literacy evaluat*[Title/Abstract] OR health literacy instrument*[Title/Abstract] OR health literacy tool*[Title/Abstract]))) AND ((child*[Title/Abstract] OR adolescent*[Title/Abstract] OR student*[Title/Abstract] OR youth[Title/Abstract] OR young people[Title/Abstract] OR teen*[Title/Abstract] OR young adult[Title/Abstract]))
#4	<u>288</u>	Search (((((((health literacy[MeSH Terms]) OR health literacy[Title/Abstract]) OR (health[Title/Abstract] AND education[Title/Abstract] AND literacy[Title/Abstract])) OR (health[Title/Abstract] AND education[Title/Abstract] AND numeracy[Title/Abstract])) AND ((health literacy assess*[Title/Abstract] OR health literacy measur*[Title/Abstract] OR health literacy evaluat*[Title/Abstract] OR health literacy instrument*[Title/Abstract] OR health literacy tool*[Title/Abstract]))
#3	<u>288</u>	Search (health literacy assess*[Title/Abstract] OR health literacy measur*[Title/Abstract] OR health literacy evaluat*[Title/Abstract] OR health literacy instrument*[Title/Abstract] OR health literacy tool*[Title/Abstract])
#2	<u>1636528</u>	Search (child*[Title/Abstract] OR adolescent*[Title/Abstract] OR student*[Title/Abstract] OR youth[Title/Abstract] OR young people[Title/Abstract] OR teen*[Title/Abstract] OR young adult[Title/Abstract])
#1	<u>8495</u>	Search (((health literacy[MeSH Terms]) OR health literacy[Title/Abstract]) OR (health[Title/Abstract] AND education[Title/Abstract] AND literacy[Title/Abstract])) OR (health[Title/Abstract] AND education[Title/Abstract] AND numeracy[Title/Abstract])

EMBASE was searched using Ovid interface on 17/02/2018 for the period 2014 to current.

Using **.mp** as searching terms (Basic Search):

Set	Results	
#1	11966	("health literacy" or (health and literacy and education)).mp.
#2	5862	limit 1 to yr="2014 -Current"
#3	639	limit 2 to (school child <7 to 12 years> or adolescent <13 to 17 years>)
#4	372	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*).mp.
#5	26	3 and 4

PsycINFO was searched using Ovid interface on 17/02/2018 for the period May 2014 to Jan 2018.

Basic Search:

Set	Results	
#1	4331	("health literacy" or (health and literacy and education)).mp.
#2	<u>2077</u>	limit 1 to yr="2014 -Current"
#3	754	limit 2 to (100 childhood <birth to age 12 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs> or 320 young adulthood <age 18 to 29 yrs>)
#4	216	(health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*).mp.
#5	40	3 and 4

CINAHL was searched using EBSCO interface on 17/02/2018 for the period May 2014 to Jan 2018.

Basic Search:

Set	Results		
S1	health literacy OR ((health AND education AND literacy))	Limiters - Published Date: 20140501-20180131; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase	View Results (467)
S2	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Published Date: 20140501-20180131; Age Groups: Child: 6-12 years, Adolescent: 13-18 years Search modes - Boolean/Phrase	View Results (118)
S3	S1 AND S2	Search modes - Boolean/Phrase	View Results (118)

ERIC was searched using EBSCO interface on 17/02/2018 for the period May 2014 to Jan 2018.

Basic Search:

Set	Results		
S1	health literacy OR ((health AND education AND literacy))	Limiters - Date Published: 20140501-20180131 Search modes - Boolean/Phrase	View Results (292)
S2	health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool*	Limiters - Date Published: 20140501-20180131 Search modes - Boolean/Phrase	View Results (13)
S3	(S1 AND S2)	Search modes - Boolean/Phrase	View Results (13)

Cochrane Library was searched on 17/02/2018 for the period May 2014 to Jan 2018.

Set	Results	Sub-database
#1	<u>2</u>	Cochrane Reviews: There are 2 results from 10210 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Year from 2014 to 2018 in Cochrane Reviews'
#2	<u>199</u>	Trials: There are 199 results from 1121096 records for your search on 'health literacy in Title, Abstract, Keywords and child* OR adolescent* OR student* OR teen* OR youth OR young adult OR young people in Title, Abstract, Keywords and health literacy assess* or health literacy measur* or health literacy evaluat* or health literacy instrument* or health literacy tool* in Title, Abstract, Keywords , Publication Year from 2014 to 2018 in Trials'
#3	201	

Appendix 3. Quality criteria for measurement properties of health literacy instruments

Property	Rating	Quality criteria	
Reliability			
Internal consistency	+	(Sub)scale unidimensional AND Cronbach's alpha(s) ≥ 0.70	
	?	Dimensionality not known OR Cronbach's alpha not determined	
	-	(Sub)scale not unidimensional OR Cronbach's alpha(s) < 0.70	
Measurement error	+	MIC > SDC OR MIC outside the LOA	
	?	MIC not defined	
Reliability	-	MIC \leq SDC OR MIC equals or inside LOA	
	+	ICC/weighted Kappa ≥ 0.70 OR Pearson's r ≥ 0.80	
	?	Neither ICC/weighted Kappa nor Pearson's r determined	
	-	ICC/weighted Kappa < 0.70 OR Pearson's r < 0.80	
Validity			
Content validity	+	The target population considers all items in the questionnaire to be relevant AND considers the questionnaire to be complete	
	?	No target population involvement	
	-	The target population considers items in the questionnaire to be irrelevant OR considers the questionnaire to be incomplete	
Construct validity			
	Structural validity	+	Factors should explain at least 50% of the variance
		?	Explained variance not mentioned
	-	Factors explain $< 50\%$ of the variance	
Hypotheses testing	+	(Correlation with an instrument measuring the same construct ≥ 0.50 OR at least 75% of the results are in accordance with the hypotheses) AND correlation with related constructs is higher than with unrelated constructs	
	?	Solely correlations determined with unrelated constructs	
	-	Correlation with an instrument measuring the same construct < 0.50 OR $< 75\%$ of the results are in accordance with the hypotheses OR correlation with related constructs is lower than with unrelated constructs	
Responsiveness			
Responsiveness	+	(Correlation with an instrument measuring the same construct ≥ 0.50 OR at least 75% of the results are in accordance with the hypotheses OR AUC ≥ 0.70) AND correlation with related constructs is higher than with unrelated constructs	
	?	Solely correlations determined with unrelated constructs	
	-	Correlation with an instrument measuring the same construct < 0.50 OR $< 75\%$ of the results are in accordance with the hypotheses OR AUC < 0.70 OR correlation with related constructs is lower than with unrelated constructs	

Note: AUC, Area Under the Curve; ICC, Intra-class Correlation Coefficient; LOA, Limits of Agreement; MIC, Minimal Important Change; SDC, Smallest Detectable Change. + positive rating; ? indeterminate rating; - negative rating.

Appendix 4. Levels of evidence for the overall rating of measurement properties

Level	Rating	Criteria
Strong	+++ or ---	Consistent findings in multiple studies of good methodological quality OR in one study of excellent methodological quality
Moderate	++ or --	Consistent findings in multiple studies of fair methodological quality OR in one study of good methodological quality
Limited	+ or -	One study of fair methodological quality
Conflicting	±	Conflicting findings
Unknown	?	Only studies of poor methodological quality

Note: + positive result; - negative result; ±conflicting result; ? unknown result.

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Appendix 5: Reliability and validity results for included instruments

Appendix Table 1. The methodological quality of each study based on reliability for each health literacy instrument

Instrument	Internal consistency		Reliability			
	Result	COSMIN score	Result	Design	Time interval	COSMIN score
NVS (Warsh <i>et al.</i> , 2014)	na	na	na	na	na	na
NVS (Driessnack <i>et al.</i> , 2014)	$\alpha=0.71$ (n=47)	Poor	na	na	na	na
NVS (Hoffman <i>et al.</i> , 2013)	$\alpha=0.67$ (n=229)	Poor	na	na	na	na
c-sTOFHLAd (Chang <i>et al.</i> , 2012)	$\alpha=0.85$ (n=300) Item-total correlation=0.44-0.86	Fair	Correlation of test and retest was 0.95 ($P<0.001$)	Test-retest	1 week	Fair
TOFHLA (Chisolm and Buchanan, 2007)	na	na	na	na	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013)	$\alpha=0.89$ (n=229)	Poor	na	na	na	na
REALM-Teen (Davis <i>et al.</i> , 2006)	$\alpha=0.94$ (n=388)	Poor	$\gamma=0.98$	Test-retest	1 week	Fair
REALM-Teen (Hoffman <i>et al.</i> , 2013)	$\alpha=0.92$ (n=229)	Poor	na	na	na	na
HLAB (Wu <i>et al.</i> , 2010)	$\alpha=0.92$ (n=275) Understanding $\alpha=0.88$ (n=275) Evaluating $\alpha=0.82$ (n=275)	Fair	Concordance rate=95%	Inter-rater	na	Poor
MMAHL(Massey <i>et al.</i> , 2013)	$\alpha=0.83$ (n=1208) Item-total correlation=0.39-0.74	Good	na	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011)	$\alpha=0.74$ (n=1316) Coefficient of reproducibility=0.84 Coefficients of scalability=0.54-0.80	Poor	na	na	na	na
DNT-39 (Mulvaney <i>et al.</i> , 2013)	$\alpha=0.93$ (n=61)	Fair	na	na	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013)	$\alpha=0.82$ (n=133) $\alpha=0.80$ (n=61)	Fair	na	na	na	na

Instrument	Internal consistency		Reliability			
	Result	COSMIN score	Result	Design	Time interval	COSMIN score
	$\alpha=0.83$ (n=72)					
eHEALS (Norman and Skinner, 2006)	$\alpha=0.88$ (n=664) Item-scale correlation coefficient=0.51-0.76	Fair	The correlations between administrations ranged 0.68-0.40.	Test-retest	Immediately after the intervention; 3-month; 6-month	Fair
CHC Test (Steckelberg <i>et al.</i> , 2009)	na	na	Cohen's Kappa was excellent for 277 ratings ($\kappa=0.9-1.0$), moderate or good for 31 ratings ($\kappa=0.7-0.89$) and poor for 5 ratings ($\kappa<0.7$)	Inter-rater	na	Poor
HKACSS (Schmidt <i>et al.</i> , 2010)	Health knowledge $\chi^2=6.45$, $P=0.17$ (n=852) Health communication $\alpha=0.73$ (n=852) Health attitudes $\alpha=0.57$ (n=852)	Excellent	na	na	na	na
HLAT-51 (Harper, 2014)	Goodness of fit statistic was calculated by each domain (CFI=0.33-0.88; TLI=0.66-0.84; RMSEA=0.09-0.17). The internal consistency statistic was not calculated.	Poor	na	na	na	na
HLAT-8 (Abel <i>et al.</i> , 2014)	$\alpha=0.64$ (n=7097 for male) $\alpha=0.65$ (n=331 for female)	Excellent	na	na	na	na
CHLT (Liu <i>et al.</i> , 2014)	$\alpha=0.87$ (the entire scale); subscales α ranged 0.59 to 0.81	Fair	na	na	na	na
VOHL (Ueno <i>et al.</i> , 2014)	na	na	The kappa value of scoring among the dentists ranged from 0.60 tooth score to 0.70 for gingiva score.	Inter-rater	na	Fair
HAS-A (Manganello <i>et al.</i> , 2015)	$\alpha=0.77$ (communication) $\alpha=0.73$ (confusion) $\alpha=0.76$ (understanding)	Fair	na	na	na	na
MaHeLi (Naigaga <i>et al.</i> 2015)	The person separation index for the original 20-item scale was 0.91 and $\alpha=0.92$. After	Fair	na	na	na	na

Instrument	Internal consistency		Reliability			
	Result	COSMIN score	Result	Design	Time interval	COSMIN score
	item reduction, the person separation index for 12-item scale was 0.90.					
QuALiSMental (de Jesus Loureiro <i>et al.</i> , 2015)	$\alpha=0.55-0.72$ (component 2 and 3) $\alpha=0.44-0.59$ (component 4) $\alpha=0.60-0.82$ (component 5)	Fair	na	na	na	na
FCCHL-AYAC (McDonald <i>et al.</i> , 2016)	$\alpha=0.73$ (FHL) $\alpha=0.63$ (IHL) $\alpha=0.85$ (CHL)	Fair	na	na	na	na
ICHL (Smith <i>et al.</i> , 2016)	na	na	na	na	na	na
HELMA (Ghanbari <i>et al.</i> , 2016)	$\alpha=0.93$ (the entire scale); subscales α ranged 0.61 to 0.89	Good	The intraclass correlation coefficient was 0.93.	Test-retest	Two weeks	Good
HLSAC (Paakkari <i>et al.</i> , 2016)	$\alpha=0.93$ (the entire scale); subscales α ranged 0.69 to 0.77	Fair	The standardised stability estimate was 0.83.	Test-retest	Two weeks	Fair
REALM-TeenS (Manganello <i>et al.</i> , 2017)	$\alpha=0.82$	Good	na	na	na	na
funHLS-YA (Tsubakita <i>et al.</i> , 2017)	$\alpha=0.75$	Fair	na	na	na	na
HLS-TCO (Intarakamhang <i>et al.</i> , 2017)	$\alpha=0.70-0.82$ for five subscales; KR-20=0.76 for health knowledge scale	Fair	na	na	na	na
HLRS-Y (Bradley-Klug <i>et al.</i> , 2017)	$\alpha=0.88$ (Knowledge) $\alpha=0.94$ (Self-advocacy/support) $\alpha=0.93$ (Resiliency)	Fair	na	na	na	na
p_HLAT-8 (Quemelo <i>et al.</i> , 2017)	$\alpha=0.74$ (the entire scale), subscales α ranged 0.41 to 0.71	Fair	na	na	na	na

Note: na, no information available. CFI, Comparative Fit Index; CHC Test, the Critical Health Competence Test; CHL, Critical Health Literacy; CHLT, Child Health Literacy Test; c-sTOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; FCCHL-AYAC, the Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; FHL, Functional Health Literacy; funHLS-YA, Functional Health

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Literacy Scale for Young Adults; HAS-A, the Health Literacy Assessment Scale for Adolescents; HELMA, the Health Literacy Measure for Adolescents; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, The Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; IHL, Interactive Health Literacy; MaHeL, the Maternal Health Literacy; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSMental, the Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, the Rapid Estimate of Adolescent Literacy in Medicine Short Form; RMSEA, Root Mean Square Error of Approximation; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TLI, Tucker-Lewis Index; TOFHLA, the Test of Functional Health Literacy in Adults; VOHL, the Visual Oral Health Literacy.

Appendix Table 2. The methodological quality of each study based on validity for each health literacy instrument

Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity		
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	
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	NVS (Warsh <i>et al.</i> , 2014)	A panel of health literacy experts developed the NVS according to previous experience. The NVS was then refined after feedback from patients, interviewers, and data analysts. No target population is involved in item generation.	Poor	na	na	Hypotheses regarding correlation between scores of a comparator instrument of Gray Silent Reading Test (GSRT) and NVS were formulated before data collection. The NVS and GSRT scores were highly correlated ($\rho=0.71$, $p<0.0001$). The NVS score increased with child age ($\rho=0.53$, $p<0.0001$).	Poor	na	na
	NVS Driessnack <i>et al.</i> , 2014)	A panel of health literacy experts developed the NVS according to previous experience. The NVS was then refined after feedback from patients, interviewers, and data analysts. No target population is involved in item generation.	Poor	na	na	A moderate positive correlation was found between children's NVS scores and their age, and between children's NVS scores and their reports of books numbers ($\gamma_s=0.43$, $p=0.003$; $\gamma_s=0.36$, $p=0.012$, respectively), but not found with their parents' report of the number of children's books at home ($\gamma_s=0.06$, $p=0.671$).	Poor	na	na
	NVS (Hoffman <i>et al.</i> , 2013)	A panel of health literacy experts developed the NVS according to previous experience. The NVS was then refined after feedback from patients, interviewers, and data analysts. No target population is involved in	Poor	na	na	Convergent validity was measured between NVS and the TerraNova academic achievement test, with a correlation coefficient of 0.49 ($p<0.01$).	Poor	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
	item generation.							
c-sTOFHLAd (Chang <i>et al.</i> , 2012)	The c-sTOFHLAd was translated from the short-version of TOFHLA according to translation procedures and was tested among 30 adolescents to ensure appropriateness.	Good	Confirmatory factor analysis was conducted to determine structural validity. One-factor model indicated an acceptable fit to the data according structural equation modelling analysis.	Fair	Convergent validity was measured between c-sTOFHLAd and the rapid estimate of adult literacy in medicine (REALM), with a correlation coefficient of 0.74 ($p<0.001$).	Fair	Semantic equivalence was measured by the content validity index (CVI). All items were rated by the experts as having a CVI>0.85. Thirty adolescents were chosen to determine and ensure the cultural congruence of the instrument.	Fair
TOFHLA (Chisolm and Buchanan, 2007)	The TOFHLA was developed from a literacy expert after reviewing commonly used hospital texts and a pilot test. No target population is involved in item generation.	Poor	na	na	The reading comprehension component was significantly correlated with the WRAT3 and the REALM ($\rho=0.59$, $p<0.001$; $\rho=0.60$, $p<0.001$ respectively), however, no correlation were found with the numeracy component ($\rho=0.11$, $p=0.45$; $\rho=0.18$, $p=0.22$ respectively).	Fair	na	na
s-TOFHLA (Hoffman <i>et al.</i> , 2013)	The s-TOFHLA was developed based on previous data analysis, perceived importance and frequency of the task in the healthcare settings.	Poor	na	na	Convergent validity was measured between NVS and the TerraNova academic achievement test, with a correlation coefficient of 0.28 ($p<0.01$).	Fair	na	na
REALM-Teen (Davis <i>et al.</i> , 2006)	The REALM-Teen was developed based on a preliminary test and a structured interview among adolescents. And a	Good	na	na	Convergent validity was measured between REALM-Teen and the WRAT-3 ($r=0.83$) and SORT-R ($r=0.93$).	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
REALM-Teen (Hoffman <i>et al.</i> , 2013)	panel of experts reviewed the word list. The REALM-Teen was developed based on a preliminary test and structured interview among adolescents. And a panel of experts reviewed the word list.	Poor	na	na	Convergent validity was measured between NVS and the TerraNova academic achievement test, with a correlation coefficient of 0.40 ($p<0.01$).	Poor	na	na
HLAB (Wu <i>et al.</i> , 2010)	Previous experience and literature review were used to develop items; 10 students were pilot-tested for appropriateness of wording, content and format of the final instrument.	Good	na	na	Correlations were assumed between socio-demographic variables and the overall scores. Socio-demographics of gender, age when came to Canada to live, speaking a language other than English were correlated with the scores of HLAB ($\beta=-0.18$, $p=0.004$; $\beta=-0.22$, $p=0.014$; $\beta=-0.20$, $p=0.008$ respectively). No convergent validity is assessed.	Fair	na	na
MAHL (Massey <i>et al.</i> , 2013)	Domains were established from literature review and focus group. Items were developed either using adaptation of existing relevant items or created by the research team.	Good	Explorative principal components factor analysis was conducted and 49.8% of the variance was accounted by 6 factors.	Good	na	na	na	na
MHL (Levin-Zamir <i>et al.</i> , 2011)	The face validity was discussed in the focus group during pilot test. The content validity was	Good	na	na	As hypothesised, MHL was associated with socio-economic determinants, particularly with gender ($\beta=1.25$, $p<0.001$) and	Good	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
	analysed using theory and operational definitions of health literacy and media literacy, and adolescents were invited to write detailed, anonymous responses.				mother's education ($\beta=0.16, p=0.04$). In addition, MHL was also associated with health behaviours ($\beta=0.03, p=0.05$) and health empowerment ($\beta=0.36, p<0.001$).			
DNT-39 (Mulvaney <i>et al.</i> , 2013)	The DNT-39 was developed from the original 43-item version DNT-43 by eliminating questions specific to type 2 diabetes. An expert team developed the DNT-43 and refined it.	Poor	na	na	The DNT-39 was associated with WRAT-3 and parent education ($\rho=0.40, p=0.001; \rho=0.29, p=0.028$ respectively)	Fair	na	na
DNT-14 (Mulvaney <i>et al.</i> , 2013)	The DNT-14 was developed from the original 15-item version DNT-15 by eliminating 1 question specific to type 2 diabetes. An expert team developed the DNT-15 by data analysis from DNT-43.	Poor	na	na	The DNT-14 was associated with the Wide-Ranging Achievement Test (WRAT3), parent education, diabetes problem solving and HbA1c ($\rho=0.36, p=0.005; \rho=0.31, p=0.019; \rho=0.27, p=0.023; \rho=-0.34, p=0.004$ respectively)	Fair	na	na
eHEALS (Norman and Skinner, 2006)	The eHEALS was developed by the expert team and pilot-tested and refined by feedback from participants.	Good	Explorative principal components factor analysis was conducted and 56% of the variance was accounted by a single factor. The factor loadings ranged from	Fair	Correlations were assumed between eHEALS and other measured variables (gender, age, use of information technology overall, self-evaluations of health). However, only gender difference was found at baseline level of eHealth literacy	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
			0.60-0.84 among the 8 items.		($t=2.236$, $p=0.026$). No convergent validity is assessed.			
CHC Test (Steckelberg <i>et al.</i> , 2009)	The CHC Test was developed by the research team and pre-tested by collecting qualitative data and quantitative field test.	Good	IRT test for determining dimensionality was performed.	Poor	na	na	na	na
HKACSS (Schmidt <i>et al.</i> , 2010)	The HKACSS items were taken from a previous health survey and selected basing on consideration of item content.	Good	na	na	As hypothesised, health communication, attitudes and self-efficacy were significantly related to each other ($\rho=0.15-0.38$, $P<0.05$). And children from higher educational background showed a better knowledge and communicated more about health topics ($\beta=0.16$, $p<0.05$).	Good	na	na
HLAT-51 (Harper, 2014)	The expert team evaluated the initial items using a 5-point Likert scale according to their research experience. And 144 college students were invited to complete a pilot test.	Good	Comprehension (CFI=0.80; TLI=0.78; RMSEA=0.09); health numeracy (CFI=0.57; TLI=0.48; RMSEA=0.09); media literacy (CFI=0.88; TLI=0.84; RMSEA=0.07); digital literacy (CFI=0.33; TLI=0.06; RMSEA=0.16); health information seeking (CFI=0.80; TLI=0.66; RMSEA=0.17)	Poor	na	na	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
HLAT-8 (Abel <i>et al.</i> , 2014)	The research team developed the HALT-8 drawing on literature review and their own experience. No target population is involved in item generation.	Poor	Explorative principal components factor analysis was conducted and 72.96% of the variance was accounted by four factors among male. In addition, the factor structure was validated using confirmatory factor analysis (CFI=0.99; TLI=0.97; RMSEA=0.03; SRMR=0.03).	Excellent	Hypotheses were formulated a priori regarding correlations between health literacy and gender, socio-cultural characteristics and health values. Results showed that female, higher educational status, and a stronger health valuation were associated with higher HL scores ($p<0.05$, respectively).	Good	na	na
CHLT (Liu <i>et al.</i> , 2014)	The research team developed the CHLT drawing on literature review, expert consultation and pilot test. 12 six graders were piloted about the instrument's readability.	Good	Confirmatory factor analysis was conducted to test the uni-dimensionality of each subscale. The factor loadings ranged from 0.20-0.58.	Fair	Hypotheses were formulated a priori regarding correlations between health literacy and gender, self-reported health and health behaviours. Results showed that female, better health status, normal BMI and healthy behaviours were positively associated with HL scores ($p<0.05$, respectively). Health-risky behaviours were negatively associated with health literacy scores ($p<0.05$).	Fair	na	na
VOHL (Ueno <i>et al.</i> , 2014)	na	na	na	na	Correlations were conducted between health literacy and gender. Results showed female students had higher gingiva scores than male students	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
HAS-A (Manganello <i>et al.</i> , 2015)	The research team developed the HAS-A drawing on literature review, expert consultation and pilot test. Scale items were piloted with undergraduates.	Good	Exploratory factor analysis was conducted and 41% of the variance was accounted by three factors.	Fair	($p < 0.05$). However, no gender differences were found regarding tooth scores.	Fair	na	na
MaHeLi (Naigaga <i>et al.</i> , 2015)	The research team developed the MaHeLi based on the health belief model and integrated model of health literacy. No target population is involved in item generation.	Poor	The health-seeking behaviour (HSB) subscale brought substantial multidimensionality into the MeHeLi scale. After removing most items of the HSB subscale, the MeHeLi scale showed a uni-dimensionality	Fair	na	na	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
			construct with some but not too noticeable multi-dimensionality.					
QuALiSMen (de Jesus Loureiro <i>et al.</i> , 2015)	The questionnaire was developed based on mental health literacy framework and adapted among Portuguese adolescents and young people.	Excellent	Exploratory factor analysis was conducted for each component of the questionnaire. A five-factor solution explained 46.84% of the total variance for component 1 and 40.00% for components 2 and 3. A three-factor solution explained 47.24% of the variance for component 4 and a two-factor solution explained 55.63% for component 5.	Fair	The relationship between mental health components and mental health help-seeking intention was examined using a binary logistic regression analysis. Results showed higher levels of mental health literacy tended to associate with mental health-seeking intentions.	Fair	na	na
FCCHL-AYAC (McDonald <i>et al.</i> , 2016)	The instrument was adapted from the functional, communicative, and critical health literacy scale to be suitable for adolescents and young adults diagnosed with cancer.	Good	Exploratory factor analysis was conducted for the entire scale. The screen plot suggested the extraction of three factors (53.1% variance explained)	Fair	Health literacy scores were examined by gender, whether the measure was completed online or on paper, whether the participant was on or off treatment. Results showed no significant difference was found.	Fair	na	na
ICHL (Smith <i>et al.</i> , 2016)	The instrument was developed from formative interviews with 20 deaf/hard-of hearing high	Good	na	na	The relationship between ICHL and standard health literacy measures were examined. Result showed most ICHL items	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
	school students. Also the instrument was piloted with 18 individuals including content-expert and content-naïve deaf and hearing colleagues, teachers interpreters and students.				were related to health literacy skills instrument-short form, s-TOFHLA, and comprehensive heart disease knowledge questionnaire ($p<0.05$).			
HELMA (Ghanbari <i>et al.</i> , 2016)	All items were initially generated by in-depth interviews with 67 adolescents. Then items were assessed by an expert panel review and 16 adolescents.	Good	Exploratory factor analysis was conducted and 53.37% of the variance was accounted by eight factors.	Good	na	na	na	na
HLSAC (Paakkari <i>et al.</i> , 2016)	The research team developed the HLSAC drawing on literature review, expert review and pilot test. Scale items were piloted with 401 pupils (7 th graders and 9 th graders).	Good	The five-factor structure was tested using confirmatory factor analysis (RMSEA=0.08; CFI=0.96; TLI=0.92; SRMR=0.03). However, due to high correlations between factors, one-factor structure was finally determined (RMSEA=0.08; CFI=0.94; TLI=0.92; SRMR=0.04).	Fair	Correlations were assumed between the final 10-item scale and the original 15-item scale. Results showed the 10-item HLSAC predicted approximately 97% of the variance of the 15-item instrument.	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity	
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score
REALM-TeenS (Manganello <i>et al.</i> , 2017)	This instrument was derived from the original 66-item REALM-Teen using the item response theory. Also, ten teenage patients were piloted.	Good	na	na	The REALM-TeenS scores were correlated with the REALM-Teen ($r=0.92$, $p<0.001$). Item fit analysis using the differential item functioning showed the REALM-TeenS functioned well for different groups of sex, race/ethnicity, and language spoken at home.	Good	na	na
funHLS-YA (Tsubakita <i>et al.</i> , 2017)	Items were generated from health materials that were frequently used in young adults and reviewed by the research team. No target population was involved in pilot test.	Poor	1-factor model was supported by the exploratory factor analysis.	Fair	The correlation between funHLS-YA and the comparator instrument of functional health literacy was 0.191 ($p<0.001$).	Fair	na	na
HLS-TCO (Intarakamha ng <i>et al.</i> , 2017)	Items were developed from theories, documents and related research. Also, focus group and expert review were used to develop the instrument. 100 samples of overweight children were piloted.	Good	Confirmatory factor analysis was conducted for each subscale and results showed the model was acceptable, with factor loading ranging 0.39-0.73.	Fair	The path model of health literacy for obesity prevention behaviours was conducted using structural equation modelling. Results showed the hypothetical causal model was consistent with empirical data ($\chi^2=60.10$, $p=0.00$, $df=12$, $RMSEA=0.05$, $CFI=0.99$; $AGFI=0.99$).	Fair	na	na
HLRS-Y (Bradley-Klug <i>et al.</i> , 2017)	Items were generated by focus group, expert review and a pilot test with 25 participants.	Excellent	Exploratory factor analysis was conducted, and results showed a three-factor structure of the instrument.	Fair	The relationships between health literacy scores and demographics were examined and results showed insurance type and knowledge, time since diagnosis and knowledge and	Fair	na	na

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Instrument	Content validity		Structural validity		Hypotheses-testing		Cross-cultural validity		
	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	Results	COSMIN score	
p_HLAT-8 (Quemelo <i>et al.</i> , 2017)	The p_HLAT-8 was translated from the HLAT-8 according to translation procedures and was tested among 10 university students to ensure appropriateness.	Good	Confirmatory factor analysis was conducted, and results showed the 4-factor model fit was fair (CFI=0.97, GFI=0.98, TLI=0.95, RMSEA=0.03).	Fair	self-advocacy.	Convergent validity was examined for each sub-scale, but the results showed that only the factor 'search for information' was adequate. Discriminant validity was only adequate for two factors ('search for information' and 'understanding information').	Fair	Three experts in the field of health forward and backward translated the scale independently. Ten university students were piloted to test and ensure the cultural congruence of the scale. Confirmatory factor analysis showed a 4-factor structure fit the model.	Fair

Note: na, no information available. AGFI, Adjusted Goodness of Fit Index; AURA, Ask, Understand, Remember and Assessment; CFI, Comparative Fit Index; CHC Test, the Critical Health Competence Test; CHLT, Child Health Literacy Test; c-sTOFHLAd, the Chinese version of short-form Test of Functional Health Literacy in Adolescents; DNT, the Diabetes Numeracy Test; eHEALS, the eHealth Literacy Scale; FCCHL-AYAC, the Functional, Communicative, and Critical Health Literacy-Adolescents and Young Adults Cancer; funHLS-YA, Functional Health Literacy Scale for Young Adults; HAS-A, the Health Literacy Assessment Scale for Adolescents; HELMA, the Health Literacy Measure for Adolescents; HKACSS, the Health Knowledge, Attitudes, Communication and Self-efficacy Scale; HLAB, Health Literacy Assessment Booklet; HLAT-8, the 8-item Health Literacy Assessment Tool; HLAT-51, the 51-item Health Literacy Assessment Tool; HLRS-Y, Health Literacy and Resiliency Scale: Youth Version; HLSAC, The Health Literacy for School-aged Children; HLS-TCO, Health Literacy Scale for Thai Childhood Overweight; ICHL, Interactive and Critical Health Literacy; MaHeLi, the Maternal Health Literacy; MHL, the Media Health Literacy; MMAHL, the Multidimensional Measure of Adolescent Health Literacy; NVS, the Newest Vital Sign; p_HLAT-8, Portuguese version of the 8-item Health Literacy Assessment Tool; QuALiSment, the Questionnaire for Assessment of Mental Health Literacy; REALM-Teen, the Rapid Estimate of Adolescent Literacy in Medicine; REALM-TeenS, the Rapid Estimate of Adolescent Literacy in Medicine Short Form; RMSEA, Root Mean Square Error of Approximation; SRMR, Standardized Root Mean Square Residual; SORT-R, Slosson Oral Reading Test-Revised; s-TOFHLA, the short-form Test of Functional Health Literacy in Adults; TLI, Tucker-Lewis Index; TOFHLA, the Test of Functional Health Literacy in Adults; VOHL, the Visual Oral Health Literacy; WRAT-3, Wide-Range Achievement Test-Revised.

Appendix Table 3. The methodological quality of each study based on responsiveness for each health literacy instrument

Instrument	Responsiveness	
	Results	CO-MIN score
VOHL (Ueno <i>et al.</i> , 2014)	Comparison of health literacy scores before and after health education showed both tooth and gingiva scores significantly increased after health education.	Fair

Note: As there was only one study examining the instrument's responsiveness, we only presented the instrument of VOHL. VOHL, the Visual Oral Health Literacy.

Research Checklist. PRISMA checklist for reporting systematic review

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-7
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	7
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Appendix 1 (CRD42018013759)
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8-9
Data collection process	10	Describe <u>method</u> of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9-10
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	10

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	10
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	11; Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	11; 15-16; Table 1 & 2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	25; Table 3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	25; Table 4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	25; Table 5
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	25; Table 5
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	32-38
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	38-39
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	39
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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