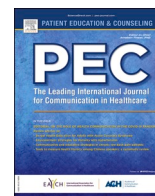




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Review article

“A bit of everything”: Health literacy interventions in chronic conditions – a systematic review



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ABSTRACT

Objective: To systematically evaluate health literacy (HL) interventions in chronic conditions by exploring theoretical perspectives, intervention content and effectiveness.

Method: We searched MEDLINE, Cochrane, CINAHL, EMBASE, ERIC, Web of Science and PsycINFO. Standardised systematic review methods were used, and sequences informing our research question were extracted and analysed. The study includes a descriptive summary of the included papers.

Results: We included 39 unique interventions, with diabetes and heart disease as the most targeted chronic conditions. Fifty-four percent of papers included a definition of HL, but the studies showed significant heterogeneity of theoretical underpinnings, modes, measures and content. We identified 23 HL measures, mostly assessing functional HL. The HL interventions were often more complex than the measures indicated. A significant change in HL was found in 28 studies. Study quality was generally poor.

Conclusions: Interventions optimizing HL appear important to improve health outcomes in chronic conditions. To ensure cumulative knowledge development of this field we need theory-based interventions, consistency in methods and more tailored and comprehensive measures to capture the interventions' complexity.

Practice implications: A more valid understanding of HL interventions and measurements is needed to reach an agreed understanding of their components and intentions.

1. Introduction

Health literacy (HL) refers to people's ability to access, understand, appraise, and use information and health services to promote and maintain good health and well-being for themselves and those around

them [1]. The skills and capacities represented by HL include people's functional literacy, interactions with others, and critical appraisal skills [2] and may be determined by the health care system and availability of resources. They represent the personal knowledge and competencies that accumulate through daily activities and social interactions and are

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transferred between generations [1]. In 2007, Paasche-Orlow and Wolf proposed a conceptual causal model to explain associations between limited health literacy and health outcomes [3]. Their model distinguishes three types of health action that mediate the impact of health literacy on health: access to and utilization of health care, patient-provider interaction, and self-care. Each of these domains is defined not only by patient factors but also by external factors that can be attributed to the health care provider or the health system. As health literacy refers to the skills people need to understand and make good decisions about their health, everyone needs health literacy skills to effectively find and access care, prevent certain health conditions, manage those that occur, communicate needs, understand their choices and make informed decisions [4].

Optimising HL has been pointed to as a possible key to decreasing the global burden of chronic conditions included non-communicable diseases (NCD) [5,6]. For people with chronic conditions, HL is especially relevant for self-management and plays a crucial role in sustainable health care interventions [7,8]. For instance, HL allows people with chronic conditions to make more autonomous decisions relating to their health and to better adapt to changing situations in everyday life [9]. Research has shown that lower HL is associated with people having less confidence when making lifestyle changes, being less proactive in health behaviors, not receiving adequate health care, denying health problems, and having poorer health outcomes compared to peers with better HL [5, 10,11]. Despite a rapid increase in publications about HL, the proportion of studies reporting on HL interventions remains remarkably low [9].

Health literacy interventions are not easy to define, as the heterogeneous results of this review underscore. However, the interventions targeted in this review are interventions aiming to increase health literacy per se and health literacy interventions aiming to improve health outcomes for people with chronic conditions. There are some reviews that refer to HL interventions. However, these reviews show mixed results when it comes to the effect of the interventions on HL and considerable heterogeneity in outcome measures in a variety of settings [7,12–14]. For example, a systematic review of HL interventions in Europe found substantial gaps in the research evidence concerning which interventions are most effective in improving HL or HL-related outcomes [15]. This review found that there were generally few studies on HL interventions and that these studies mainly targeted reading and numeracy aspects of HL (i.e functional HL). A lack of evidence of the effectiveness of interventions aiming at interactive or critical HL has been reported [15].

Furthermore, a review of HL interventions in primary care could not identify one intervention type that was more effective for changes in behavioral risk factors for chronic disease [16]. There have been some diagnosis-specific reviews on HL interventions in chronic conditions, such as COPD and asthma [17], cancer [18], congenital heart conditions [19], kidney disease [20], and diabetes [11], all of which mainly focus on describing outcome measures. In general, a wide range of measurements have been developed to assess skills or screen for inadequate HL [13,17,21,22]. Although these instruments have been used with several patient populations, their usefulness and applicability for people with chronic conditions remain largely unknown.

To the best of our knowledge, previous reviews on HL interventions in the context of chronic conditions have mainly focused on the strength of evidence by investigating the effectiveness and methodological quality. However, the strength of evidence is also connected to theoretical consistency, the content of interventions and instruments for assessing their outcomes, aspects for which there is a knowledge gap in existing systematic reviews on HL. Knowledge about the strength of evidence, including investigation of conceptual and methodological consistency, will illuminate the current state of the art and point to eventual needs for further research on effective HL interventions for chronic conditions in health care practice. Hence, the current review aims to extend previous reviews on HL interventions by more thoroughly investigating the evidence of HL interventions by focusing on

conceptual and methodological aspects across and within the interventions. The following research question is raised: What do we know about the content, the theoretical perspectives and the effectiveness of HL interventions for patients with chronic conditions?

2. Methods

2.1. Design and registration

An a priori protocol was published in the International Prospective Register of Systematic Reviews (PROSPERO) (<http://www.crd.york.ac.uk/PROSPERO>) (ID: CRD42020180678). The research group comprised fourteen researchers (from young researchers to professors with extensive research experience), all with a professional background in either nursing or physiotherapy, and an experienced research librarian, creating a team with broad qualifications in quantitative and qualitative research on patients with chronic conditions. Many of the participants in the research team have extensive experience in health literacy research, including theory and outcome measure development and development and testing of health literacy interventions. Hence, we had both an outsider and insider perspective on HL, which allowed us to raise varied critical questions, even those that are not usually asked within the field.

2.2. Search strategy, selection and data extraction

This systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines [23]. The search strategy was developed in MEDLINE (Ovid) by an experienced research librarian (KM). The searches were based on the researchers' experience, former systematic reviews, key articles, and searches using the MeSH-term "Health Literacy" to explore which terms were used to describe the topic. A sensitive filter based on Ovid Expert searches was developed and added to the search strategy to limit the search results to quantitative studies' as described in the inclusion criteria (<https://tools.ovid.com/ovidtools/expertsearches.html>).

The librarian presented results from an initial test search for the researchers to see if the results were accurate. We excluded the keyword "chronic illness" from the search to avoid missing studies discussing chronic conditions without using text words indicating that the condition is, in fact, chronic. We searched only for articles published after 2010 to ensure that the included articles were relevant to an evolving health care system within chronic care. We also chose 2010 as a starting point as HL interventions prior to 2010 probably only include functional HL outcome measures (measuring reading comprehension and numeracy). Therefore, we made a pragmatic choice choosing 2010, thereby hopefully also including interventional studies with more comprehensive novel HL measures [24].

After reaching a consensus regarding search strategy, the strategy was translated to CINAHL (EBSCOhost), Cochrane (limited to Trials), EMBASE (Ovid), ERIC (EBSCOhost), PsycINFO (Ovid), and Web of Science (Core collection), and peer-reviewed according to the Peer Review of Electronic Search Strategies (PRESS) guidelines [25] by another experienced research librarian. In addition, the librarian has conducted forwards and backwards citation tracking of key articles to identify other relevant studies. The search was conducted in the chosen databases (11 May 2020), and results were exported to EndNote and duplicates were identified and removed. The search strategies for Medline and Cinahl are presented in [Supplementary file 1](#).

In selecting health literacy interventions, we have chosen to take a broad empirical approach to ensure that our review comprised data richness and variety. Hence, health literacy interventions or programs (as defined in the particular study) or interventions aiming to strengthen/ support/ increase health literacy delivered in inpatient, outpatient, or community settings and that included a measure of HL (defined by the study) were eligible for inclusion.

The remaining papers were randomly divided into seven parts, and

each part was imported into the web application Rayyan (www.rayyan.ai) for storage, organization, blinding and screening of title and abstracts for the designated review pairs.

Based on the inclusion and exclusion criteria (see Table 1), the fourteen researchers were divided into seven pairs who, after the first independent screening of titles and abstracts, reviewed the full-text papers to assess eligibility for inclusion. Hence, we applied a two-step blinded process. The pairs also manually searched the reference list of the included articles after full-text assessment to identify additional papers.

Due to lack of funding for translation, we included only studies in English, German and Nordic languages; however, the search strategy had no language filters. Articles that did not present a clear HL outcome had to state that they presented an HL intervention if they were to be included.

To enhance reflexivity, articles were rotated between the pairs of researchers in the process of inclusion/exclusion, data extraction and quality assessment. Each pair included at least one experienced HL researcher. When there were disagreements or uncertainties, a group of four researchers (MHL, AKW, AMM, MHA) assessed whether a publication met the inclusion criteria.

The pairs of researchers extracted data from the included publications using a standardized pre-defined data charting form including authors, year of publication, area of origin, participant diagnoses, study design, setting, inclusion or absence of a definition of HL, use of theoretical perspectives, mode of intervention, and HL-related outcome measures.

2.3. Qualitative analysis of the intervention content

The included papers were again distributed to the pairs of group members in order to identify descriptions of the HL interventions in each paper. The two members of each pair received in this stage a new pile of papers. They read each paper independently and extracted relevant texts. After that, the pairs met to compare their results and agree on relevant extracts for further analysis, and these extracts were coded. Then, the whole group met and discussed codes and overall impressions of what was addressed in the descriptions of the HL interventions. Our shared impression was that the papers included information about theoretical understandings or definitions, delivery modes, educational approaches, and evaluations. Four researchers (MHL, AKW, AMM, MHA) reread the extracts and sorted them under these themes inspired by the overall impressions. This work was done with the help of NVivo 12 [26] across the included papers (n = 39). Finally, two researchers (AKW, MHL) wrote up the results of this analysis which were then discussed with the whole review group, these results are presented in a total of nine headings in 3.2.

Table 1
Exclusion/inclusion criteria in PICO format.

	INCLUSION CRITERIA	EXCLUSION CRITERIA
Participants (P)	Patients diagnosed with a chronic disease > 18 years	Children and adolescents with a chronic disease
Interventions (I)	Health literacy interventions or programs (as defined in the particular study) or interventions aiming to strengthen/ support/ increase health literacy delivered in inpatient, outpatient, or community settings and include a measure of HL (defined by the study).	Interventions not declared to be a health literacy intervention or measuring HL (i.e. self-management, self-care, empowerment interventions)
Comparisons (C)	No treatment control groups, waitlist, attention control groups (participants receive some other attention) or standard care control groups, pre/post comparisons.	Studies without a comparison
Outcomes (O)	The included studies must measure health literacy (HL outcome defined by the study). We choose to take a holistic approach and look at all parameters claiming to measure HL.	Study endpoints (outcomes) not defined in the study as measuring HL (included studies where health literacy is studied as a mediator).
Design	Original research of quantitative design: RCT, quasi-experimental designs	Cross-sectional designs, qualitative research, different types of reviews,
Language	English, German, Scandinavian	All other languages
Other characteristics		non-peer-reviewed studies

2.4. Quality assessment

Quality of the primary studies was assessed based on the research design. We used the updated Cochrane Risk of Bias Assessment tool (ROB2) for randomized controlled trials (RCTs) [27]. Using the provided template and algorithm, structured evaluations were made of bias arising (a) from the randomization process, (b) deviation from the intended intervention, (c) missing outcome data, (d) measurement of the outcome, and (e) selection of the reported results. An overall judgment can be derived from assessing these five domains as having a low risk of bias, some concerns about bias, or a high risk of bias [27]. We used the Joanna Briggs Institute Checklist for Quasi-experimental Studies with nine questions [28]. All quality assessments were independently conducted in the review pairs before their consensus, and any conflicts were discussed.

2.5. Data synthesis and analysis

The goal of the systematic review was to provide a quantitative assessment of the effects of the HL interventions (planning to pool the effect sizes using a random effect model for each mode (i.e group, individual, remote) and outcome and estimate an associated 95% CI). However, we found significant variability in the contents of HL interventions, chronic diseases and outcomes, and therefore, we used a narrative approach to data synthesis. To assist in assessing effectiveness across this large number of studies, we tabulated the primary outcome of each of the studies, a summary of the HL result, and whether the changes were statistically significant. We determined the proportion of studies with positive HL outcome results (primary or secondary).

3. Results

3.1. Characteristics of included studies

We retrieved 3882 articles after the removal of duplicates; 3665 articles were excluded based on the title, abstract, and keywords. After the first screening, 217 articles were included and assessed in full text. Following the full-text review, 62 articles were included, but during the quality assessment and the analysis of the interventions, 23 more studies were excluded as they did not meet our inclusion criteria. These late exclusions were mainly because the studies either did not measure HL post-intervention or did not claim to be an HL intervention. Thus, a total of 39 articles were included in our review. Fig. 1 shows the steps of the search and selection process.

Of the 39 included studies, 26 of the studies were RCTs (including two pilot RCT studies), 6 had a quasi-randomized design [29–34], (where two studies were non-randomized [29,31], and 7 had a pre/post design [35–41]). Two studies from Denmark reported on the same

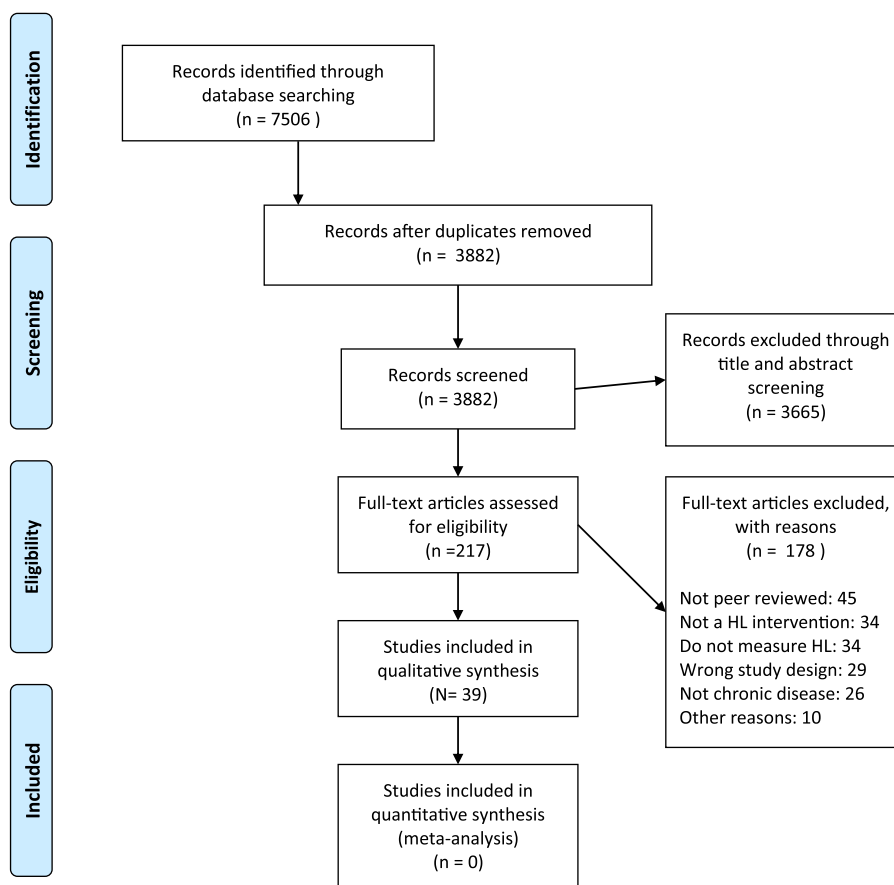


Fig. 1. The Prisma flow chart.

intervention with different samples [42,43].

The interventions included 10,292 participants, with study samples varying from 29 to 1668 participants. Five studies only included older participants (> 55 years) [44–48]. The 39 studies included patients with various chronic conditions: 15 studies included patients with diabetes [30,33,34,40,41,45,49–57], 6 included patients with different cardiovascular diseases [31,35,39,58–60], five studies included patients with high blood pressure [37,41,48,61,62], five studies included persons with cancer or cancer survivors [38,63–66], and three included individuals with COPD [42,43,52] (see Table 2). Six studies included other chronic conditions, (i.e. depression (n = 1) [67], HIV (n = 3) [32, 68, 69], and unspecified chronic conditions [29,46]). Additionally, three of the studies mentioned above included persons with more than one chronic condition [29, 41, 52]. The settings of the interventions varied; 12 studies were conducted in hospitals or specialist clinics [31, 34, 38, 41, 49, 54, 56, 58, 60, 63–65], 22 were conducted in different community settings (i.e. primary care/health clinic [30, 32, 35, 39, 50, 51, 57, 61, 68] general practices [40, 52, 55, 67], senior centers [45,46] and pharmacies [44,59], health centres and churches [33, 37, 48, 62, 66]. Three interventions were home based [29, 43, 69] and two were in a combined home and health care setting [31,42]. One study had different settings in different countries (primary care practice, diabetes outpatient clinics and diabetes support groups) [53].

Most studies (15/39, =38.5%) were conducted in the United States; thirteen studies were conducted in Asia (China[57,62], Taiwan [64], Thailand [34] Korea[45,49], Japan [56], Iran [46, 54, 60, 61, 63, 65]) (=33%), six in Western Europe (Denmark [31, 42, 43], UK [53,67], Germany [55]) (=15%), three in Australia [29, 35, 52] (=8%), and one study each in Brasil [30], and Canada [39]. A total of 23 (=59%) of the articles were published in 2018 or later.

3.2. Content and conceptual aspects of the interventions

Twenty-one studies (54%) presented a definition of HL. In total, nine different definitions were used; the most common definition were those provided by the World Health Organization (WHO) (1986) [70] (n = 4), by Nutbeam (1998) [71] (n = 4), by the Institute of Medicine (2004) [35,72] (n = 4) and by Sørensen (2012) [73] (n = 4). (see Table 3).

The qualitative analysis of the texts describing the interventions illuminated themes such as development and theoretical underpinnings, the content of interventions and educational approaches, mode, time-frame and support materials and providers of delivery. Within each of these themes, different approaches and variations were described: in many ways, a bit of everything.

Intervention development ranged from bottom-up [48] to top-down. In many cases, different stakeholders were included in the development of the intervention content (bottom-up), and interventions seem to have been pragmatically developed based on what was possible within a particular context. In other cases, interventions were developed based on literature reviews, previously described components or theories (top-down).

With regard to **theoretical underpinnings**, the interventions were based on a broad range of definitions and models of HL focusing on different aspects of the concept [37,74] (see Table 3). However, other models and frameworks from related fields such as self-management [62,75], other motivational, cognitive and behavioural frameworks, and whole-system approaches [36,62] were described as theoretical underpinnings.

The **content of the interventions** represented a variety of topics and contexts targeting HL tasks and skills, such as knowledge and communicational skills essential to a specific intent. Frequent topics were healthy behaviour, medication adherence [28,44] and

Table 2
Study characteristics.

Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No	Setting (S)/ Mode of the intervention (M)	HL outcome: Primary = 1, Secondary = 2 Not described =ND	Findings related to HL
1 Bahrami et al. 2019 Iran	SD: RCT design S: N = 60 women (intervention group: 30 /control group:30)	Breast cancer (anxiety) Aim: to investigate the effect of a health literacy promotion program on the level of health literacy and death anxiety in women with breast cancer	NO	S: Specialist health care M: (1) an individual educational programme consisting of four sessions arranged once every two weeks for the intervention group	2: The Health Literacy For Women with Breast Cancer (HELBA) questionnaire	Significant differences in the level of health literacy immediately after the intervention ($Z = 4.74$, $p < 0.001$) and 1 month later ($Z = 4.92$, $p < 0.001$) between the study and control group. The use of a health literacy promotion program for women with breast cancer might increase their health literacy.
2 Banbury et al. 2020 Australia	SD: Mixed method Quasi-experimental non-randomized S: N = 111 (IG:52/ CG: 60)	At least one chronic condition Aim: to evaluate the intervention's effectiveness for improving health literacy, CDSM and perception of social support	YES (Nutbeam's definition)	S: Home M: (2) Group, web-based intervention. The intervention group participated in five, weekly videoconference group meetings (1.5 h), the control group had only remote monitoring.	1: Health Literacy Questionnaire (HLQ) 2. 2 scales on Health Education Impact Questionnaire (heiQ)	The three-month follow-up found minor effects in the intervention group only, with improved health literacy behaviors (five HLQ scales) and self-management skills (two heiQ scales), (Effect size 0.11–0.45). No significant interaction between the intervention and control groups and time.)
3 Carroll et al. 2019 United States	SD: RCT design S: N = 360 (IG: 180 / CG: 179)	Persons living with HIV (PLWH) Aim: to evaluate the effect of a multimodal self-management program (peer led)	NO	S: Primary care M: (3) Combi, six 90-min group training sessions using an e-Personal Health Record and a single 20–30 min individual pre-visit coaching session	2: e-health literacy scale (e-Heals)	The intervention group significantly improved e-Heals (difference 2.67: 95% CI 1.38–3.9) compared to controls. The eHealth literacy effects were more substantial for minority participants.
4 Crengle et al. 2018 Australia, Canada and New Zealand	SD: Pre/post design S: N = 171	Indigenous people with cardiovascular disease (CVD) Aim: to assess the effect of a customised, structured CVD programme on medication knowledge among Indigenous people with, or at high risk of, CVD medication health literacy	NO	S: Indigenous primary care services M: (1)An individual education delivered on three occasions over 1 month by registered nurses or health educators	ND: health literacy practices/ knowledge of CVD medication	Adjusted analyses showed highly significant ($P < 0.001$) increases in knowledge scores between pre-session and post-session assessments at all three-time points for all medication classes.
Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No (Reference)	Setting (S)/ Mode of the intervention (M)	HL outcome: Primary = 1, Secondary = 2, Not described = ND	Findings related to HL
5 DeWalt et al. 2012 United States	SD: multisite RCT design S: N = 605	Heart failure (HF) Aim: to compare the effects of 2 different amounts of self-care training on the incidence of all-cause hospitalization and death	NO	S: Outpatient (general internal medicine and cardiology clinics at 4 sites) M: (1) Individual. 1) a single session (40-minute in-person, literacy-sensitive training) or 2) multisession (the same initial training and then ongoing telephone-based support)	ND: S-TOFHLA	A more intensive multisession intervention for patients with HF did not decrease the incidence of hospitalizations compared with a single session only. Patients in the multi-session group had more improvement in HFQOL from baseline at the 1-month and 6-month ($P < 0.001$)
6 Dos Santos 2019 Brasil	SD: Quasi randomized design S: N = 55	Diabetes type 2 Aim: to evaluate the effect of a educational intervention in the adherence to selfcare and functional health literacy and numeracy	YES (WHO definition of HL)	S: Primary care/health clinic M: (2) three group meetings with nurse and roundtable discussions on knowledge, self-care and foot care	1: Questionário de Atividades para Autocuidado com o Diabetes	Educational interventions had a positive effect on adherence to self-care and functional literacy in health. The greatest difference after the intervention for self-care was the item “inspecting the inside of the shoes before putting them on”, with 3.29 days in the week delta.

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Table 2 (continued)

Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No	Setting (S)/ Mode of the intervention (M)	HL outcome: Primary = 1, Secondary = 2 Not described =ND	Findings related to HL
ws7 Dworkin et al. 2019 United States	SD: Prospective Pre/ post design (pilot) S: N = 43 African American men	HIV positive men Aim: feasibility, acceptability, and preliminary efficacy of a theory-based mobile-delivered embodied conversational agent intervention	NO	S: Home M: (1) Individual, using the mobile app + two check-in phone call by the project staff (technical problems).	2: HL was measured as baseline versus follow-up knowledge of information that was taught in the app	A statistically significant change in knowledge was observed for knowing what is a viral load (increasing more than 10% from baseline), what is a CD4 count (increasing more than 30% from baseline), and if their medication has to be taken with food (increasing nearly 40% from baseline and rising to > 90%).
8 Han et al. 2018 United States	SD: A single-arm pre- and post-test design S: N = 17 (N = 11 post intervention)	Latinos with uncontrolled high blood pressure (HBP) Aim: to test the acceptability and efficacy of a HL-focused HBP intervention in Spanish-speaking Latinos with uncontrolled HBP	Unclear (Osborne, 2010)	S: Community health center or ethnical church M: (3) 4 weekly gr. sessions for HL training combined with disease knowledge education in HBP management, followed by phone counseling and text messages	1: HBP-health literacy scale (HBP-HLS) and the Newest Vital Sign	Improved BP, numeracy, and psychological outcomes were observed. For health literacy and psychosocial variables, the effect sizes ranged from 0.1 to 1.7 in absolute value. Mean change in HBP health literacy-reading 0.1 (SD 1.5), effect size 0.1.
Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No (Reference)	Setting (S)/ Mode of the intervention (M)	HL outcome: Primary = 1, Secondary = 2 Not described ND	Findings related to HL
9 Huang et al. 2018 Taiwan	SD: RCT design S: N = 99 (IG:49 / CG:50)	Postoperative Patients with breast cancer Aim: to develop a tailored rehabilitation education programme and examine its effectiveness	WHO's definition of HL	S: Hospital + out patient clinic M: (1) Individual, 4 post- op visits from the occupational therapist using teach back	1: HLS -EU-47 + HLS- EU Q16	Significant improvements in HL and health status. The mean HL score differences after intervention in the intervention group versus the control group were 5.54 ± 6.47 versus - 1.70 ± 7.27 (Cohen d=1.05, P < .001) for general HL, 6.27 ± 6.29 versus 0.48 ± 6.34 (Cohen d=0.92, P < .001) for the HC domain of HL, 5.89 ± 7.41 versus- 0.98 ± 9.51 (Cohen d=0.82, P < .001) for the DP domain of HL, and 7.93 ± 8.56 versus - 1.75 ± 10.25 (Cohen d=1.03, P < .001) for the HP domain
10 Hæsum et al. 2017 Denmark	SD: RCT design S: N = 90 (IG:47/ CG:43)	Patients with COPD Aim: to explore how the use of the Telekit affects the level of FHL over 10-months.	WHO's definition of HL	S: community care /home M: (4) Remote, a telehomecare solution (The Telekit) that transmits relevant patient data + provides instructions on how to manage exacerbations.	1: Danish Test of Functional Health Literacy in Adults (TOFHLA)	A significant increase in functional health literacy is observed in both the groups from baseline to follow-up, but there is no statistical difference between groups (P-value = 0.62)
11 Hæsum et al. 2016 Denmark	SD: RCT design S: N = 116 (IG: 60/ CG: 56)	Patients with COPD Aim: to explore whether the level of FHL is affected by introducing the Telekit and its associated educational components	Nutbeam's definition	S: Home based M: (4) Remote, introduction of a telehomecare intervention (Telekit)	The Danish Test of Functional Health Literacy in Adults (TOFHLA)	No statistically significant difference between the intervention and control groups = the introduction of the Telekit and its associated educational components has no effect on functional health literacy.
12 Kim KB 2014 United States	SD: RCT design S: N = 369 (IG: 184 / CG: 185)	Korean American Seniors with High Blood Pressure Aim: to explore effect of a multimodal Self-Help Intervention Program on the Control of HBP	NO	S: Churches and senior centers M: (3) 6 weekly educational sessions on HBP management including HL training, + telephone counseling and home blood pressure (BP) monitoring (12 mts)	HBP health literacy scale	Health literacy scores showed no difference between the two groups at six months, but there were significant differences in both print and functional health literacy scores at 12 and 18 months (p < 0.05).

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Table 2 (continued)

Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No	Setting (S)/ Mode of the intervention (M)	HL outcome: Primary = 1, Secondary = 2 Not described =ND	Findings related to HL	
13	Kim et al. 2019 South Korea	SD: RCT design using three parallel groups S: N = 151 (IG: 50 +50, CG: 51)	Type 2 diabetes Aim: to evaluate the effects of a social media-based, HL-diabetes management intervention compared to telephone-based, HL diabetes management intervention and usual care	NO	S: endocrinology outpatient units at two general hospitals, M: (1) initial face-to-face diabetes nurse education and weekly action-planning sessions	ND: Short Form of the Korean Functional Health Literacy Test	In the analysis of treatment by health literacy level interaction, there was a significant interaction effect for patient activation level [F(2, 140) = 3.55, p = .031, observed power = .65. No between group differences otherwise.
14	Kim et al. 2020 United States	SD: RCT design S: N = 250 (IG: 120/ CG: 130)	Korean Americans with type 2 diabetes Aim: to empirically examine underlying mechanisms of health literacy's role in diabetes management	NO	S: Primary care /health clinic M: (3) Combination intervention; 1) weekly 2-hour didactic classes for 6 weeks, totaling 12 h; 2) monthly telephone counselling, 3) daily home monitoring of blood sugar	1: TOFHLA + Newest Vital Sign 2: The original REALM and the diabetes specific DM-REALM	The differences between the two groups in improvement from baseline were all statistically significant, except for the changes in TOFHLA scores at months 6 and 12. The direct effect of HL on self-efficacy was statistically significant (b = .172, SE = .035, p < .001),
15	Knudsen et al. 2020 Denmark	SD: Quasi -experimental (non randomized) pilot study. S: N = 77 (IG: 24, CG: 53)	Diverse heart surgery patients. Aim: to evaluate patient activation and HL in tele-rehabilitation compared to hospital-based cardiac rehabilitation.	Sørensen's definition	S: Hospital / home M: (4) primarily remote Individual 12 weeks tele- rehabilitation and hospital based cardiac rehabilitation	Three dimensions from the Health Literacy Questionnaire (HLQ = HLQ3, HLQ9, HLQ6)	Tele-rehabilitation and hospital-based cardiac rehabilitation seemed equally successful in improving HL. No sign between-group differences. From baseline to six-month follow-up, the intervention group improved its 'ability to engage with healthcare providers' (HLQ6) significantly more than controls, by 0.4 points (95% CI: 0.04–0.67; p = 0.003). Controls sign. reduced ability to engage with healthcare providers by 0.13 points (95% CI: -0.25– -0.01) at six-month follow-up (p = 0.03).
16	Koonce et al. 2015 United States	SD: RCT design S: N = 160 (IG: 81, CG: 79)	Diabetes type 2 patients Aim: to test the generalizability of an individualized information prescription model	No (Reference)	S: Community care clinics M: (1) Individual intervention. The intervention group received educational materials targeted to health literacy levels and learning styles.	3-questions: how confident they are filling out forms, how often they need help reading hospital materials, and how often they have trouble learning about medical conditions.	The mean number of diabetes knowledge questions answered correctly by the intervention group increased significantly after 2 weeks ($\Delta = 2.66$, P = 0.000), which persisted at 6 weeks ($\Delta = 2.46$, P = 0.00). The control group showed no difference.
17	Lee et al. 2018 United States	SD: prospective, multisite, randomized-controlled, pre-post interventional trial S: N = 92 (IG: 49, CG: 43)	Adults > 55 years, taking 2 or more prescription medications for a chronic condition(s). Aim: to assess the effectiveness of the educational intervention to improve prescription label understanding	NO	S: Two senior centers, five community pharmacies. M: (1) Individual, study group received short, focused, in-person, one-on-one education about identifying critical information on the redesigned prescription label + brochure; control group, no education or brochure	prescription label comprehension survey (MLT), & pillbox fill test.(MLT was used as a proxy for FHL)	There was an increase in Pillbox Fill pre-post score in the intervention group. A significant positive correlation was observed between Rx label comprehension and FHL. Analysis of covariance (ANCOVA) did not show any significant study group effect on the MLT post-score after controlling for MLT pre-score (p = 0.57).

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Table 2 (continued)

Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No	Setting (S)/ Mode of the intervention (M)	HL outcome: Primary = 1, Secondary = 2 Not described =ND	Findings related to HL
18 Lee et al. 2017 Korea	SD: RCT design S: N = 51 (IG: 26, CG: 25)	Korean older adults with diabetes Aim: to evaluate the effects of a HL-considered diabetes SM program on diabetes-related parameters	Nutbeam's definition	S: Two senior centers M: (2) Group based Interventional group attended weekly 1-hour sessions for 12 weeks to learn how to manage diabetes.	Korean Health Literacy Assessment Tool	The health literacy score of the intervention group (mean [SD] = 44.4 [17]) was lower than that of the control group (mean [SD] = 48 [12.6]) in the posttest ($p < 0.05$). It was significant posttest differences between groups in diabetes self management knowledge ($p = 0.046$), self-efficacy ($p = 0.046$), self management behaviour ($p = 0.012$), and self-monitored blood glucose subscale ($p = 0.002$).
Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No (Reference)	Setting (S)/ Mode of the intervention (M)	HL outcome / primary = 1, Secondary = 2 Not described =ND	Findings related to HL
19 Mudiyansele et al. 2019 Australia	SD: single blinded RCT design (pilot) S: N = 171 (IG: 86, CG: 85)	Diabetes & COPD Aim: to assess the impact of home-based telehealth monitoring on health outcomes, quality of life and costs	NO	S: Community based M: (4) Remote Individual, Standard care versus home-based telehealth	2: Health Education Impact Questionnaire (heiQ) (named as HL outcome)	The intervention group showed an improvement in health literacy at 12 months) = a statistically significant difference between the two-time points, (P-values 0.018–0.08) in 4 heiQ domains (out of eight). HL outcomes, including attitudes and intentions to engage in physical activity, significantly improved following the intervention in both intervention groups. Participants with higher levels of HL were significantly more likely to complete more sections of the intervention (mean difference 0.25, 95% CI 0.05–0.45, $P = .02$)
20 Muller et al. 2017 United Kingdom	SD: RCT design S: N = 1041 (IG: 544, CG: 497)	Type 2 diabetes Aim: to develop a Web-based intervention promoting physical activity among people with type 2 diabetes	Sørensen's definition	S: Varied in the different countries M: (4) Remote individual intervention, a Web-based intervention (one interactive and one plain-text version) to promote physical activity	(1) diabetes knowledge, (2) pati. enablement, (3) attitude, behavioral control, and intention to do physical activity	HL outcomes, including attitudes and intentions to engage in physical activity, significantly improved following the intervention in both intervention groups. Participants with higher levels of HL were significantly more likely to complete more sections of the intervention (mean difference 0.25, 95% CI 0.05–0.45, $P = .02$)
21 Nahm et al. 2019 United States	SD: one-group pre-/post-test design study S: N = 30	Cancer survivors Aim: to evaluate an interactive electronic Cancer Survivorship Patient Engagement Toolkit (CaS-PET)	NO	S: University Cancer Center M: (4) Remote. The intervention delivered survivorship care plans, biweekly follow-up using patient portal e-messages, and online resources	eHealth Literacy Scale	The e-health literacy outcome showed improvement, but the increase was not statistically significant (Beta 1.43 (CI –0.46, 3.33), $p = 0.133$).
22 Negarandeh et al. 2013 Iran	SD: RCT design S: N = 127 (Pictorial image group N = 44, Teach back group N = 43, Control group N = 40)	Type 2 diabetes Aim: to explore the impact of pictorial image and teach back educational strategies on knowledge, adherence to medication and diet among patients with type 2 diabetes	YES Ratzan & Parker 2000	S: Secondary care level diabetes clinic - outpatient care by physicians and nurse educators. M: (2) Group. 3 arms of the study (pictorial image, teach back, and control groups). The two IG received education in 3 weekly sessions (each 20 min).	TOFHLA	Mean scores of knowledge, adherence to medication and diet revealed significant differences between two intervention groups and control group ($P < 0/001$) six weeks after intervention. Both educational strategies seem to be effective for patients with low health literacy
Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No (Reference)	Setting (S)/ Mode of the intervention (M)	HL outcome / Primary = 1, Secondary = 2 Not described =ND	Findings related to HL
23 Nokes et al. 2019. United States	SD: quasi-experimental, nonequivalent two-group design S: N = 100 (IG: 50, CG: 50)	Low-income persons living with HIV/ acquired immune deficiency syndrome Aim: to explore whether a brief educational intervention using a	NO	S: Adult Day Health Care Center (ADHC) programme M: (2) Group. A brief educational intervention using the National Library of Medicine video +given an	The electronic Health Literacy Scale (eHEALS)	Statistically significant differences in electronic health literacy from baseline to immediately after the first session for both groups (MEDLINE: $df = 98$, $t = -5.020$, $P = .000$; E-HELP: (continued on next page)

Table 2 (continued)

Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No	Setting (S)/ Mode of the intervention (M)	HL outcome: Primary = 1, Secondary = 2 Not described =ND	Findings related to HL	
		video, Evaluating Health Information, would increase electronic HL		at-home assignment. Participants in the E-HELP group received an additional 15 min with the HIV nurse clinician using teach back.		df = 98, t = -7.140, P = .000). The electronic health literacy was statistically significantly higher 1 week later compared to baseline (MEDLINE: df = 98, t = -4.720, P = .003; E-HELP: df = 98, t = -7.740, P = .000).	
24	Noureldin et al. 2012 United States	SD: Post hoc analysis of a randomized controlled trial S: N = 314 (IG: 122 CG:192)	Patients with heart failure Aim: to assess the effect of HL on drug adherence in the context of a pharmacist-based intervention	YES, Kutner, Jin, Paulsen. The health literacy of America's adults (2003)	S: Primary Care Center pharmacy M: (1) Individual pharmacist-based intervention; patient education, therapeutic monitoring, communication with primary care providers	The Short Test of Functional Health Literacy in Adults (STOFHLA)	Patients with adequate HL have better adherence to cardiovascular drugs than those with inadequate HL. The pharmacist intervention improved adherence in patients with adequate and inadequate HL.
25	Prabsangob et al. 2019 Thailand	SD: A quasi-experimental study design S: N = 70 (IG: 35, CG: 35)	T2DM patients Aim: to test the effectiveness of a self-help group programme across three months	NO	S: Registered at community hospitals in a rural Thai community M: (2) Group. A self-help group (SHG) programme based on the concept of social cognitive theory	Un-named health literacy measure	Following three months of intervention, health literacy, self-care behaviors and HbA1c levels were significantly improved in the intervention group compared to the control groups (p < 0.05).
26	Rastegar et al. 2020 Iran	SD: RCT design S: N = 72 (IG: 36, CG: 36)	Women with breast cancer Aim: to investigate the effect of HL counselling on self-care in women after mastectomy	NO	S: Motahari Chemotherapy Clinic in Fars Province M: (2) Group. Six 1.30-hour sessions were held for both the intervention and control groups.	The Iranian Health Literacy Questionnaire (IHLQ)	In the intervention group, the mean score of the dimensions of health literacy increased immediately and three weeks after the intervention. The two groups differed significantly in terms of the overall mean scores of health literacy over time (P < 0.001).
Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No (Reference)	Setting (S)/ Mode of the intervention (M)	HL outcome / primary outcome= 1, Secondary outcome= 2 Not described = ND	Findings related to HL	
27	Rust et al. 2015 United States	SD; A pilot randomized controlled study (N = 48, IG: 24, CG: 24)	African-American breast cancer survivors Aim: to provide information addressing HL with respect to medication adherence and self-efficacy in African American breast cancer survivors	NO	S: Community-based organization for underserved and minority women M: (2) Group. The Medication Adherence Skills Training (MST) group participated in a two hour group workshop conducted by a pharmacist.	Chew Subjective Literacy Screening	Analysis of the intervention and treatment groups did not show a statistically significant effect on health literacy, medication adherence, or self-efficacy from pretest to post-test.
28	Salisbury et al. 2016 United Kingdom	SD: a pragmatic, multicentre, randomized controlled trial S: N = 609 (IG: 307, CG: 302)	Patients with depression Aim: To compare the Healthlines Depression Service plus usual care with usual care alone	NO	S: 43 general practices in UK M: (4) Remote, regular telephone calls from a health adviser supported by interactive software for effective use of telehealth to improve management of chronic disorders—the Telehealth in CHronic disease (TECH) model	2: eHEALS	Compared with usual care alone, intervention participants reported improvements in anxiety, better access to support and advice, greater satisfaction with the support they received, and improvements in self-management and health literacy
29	Seidling et al. 2020 Germany	SD: unblinded, exploratory, prospective, randomized controlled study S: N = 113 (IG: 55 CG 58)	Community-dwelling patients with type 2 diabetes mellitus. Aim: to assess the influence of a medication module within a patient-led electronic health record on patients' HL	Sørensen's definition	S: Primary care practices. M: (4) Remote Individual. Patients either had access to an internet-based medication module (intervention group), or they received an information brochure (control group).	1: The Health Literacy Questionnaire (HLQ)	No differences in overall health literacy were observed in either the intention-to-treat or in the per-protocol cohorts.

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Table 2 (continued)

Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No	Setting (S)/ Mode of the intervention (M)	HL outcome: Primary = 1, Secondary = 2 Not described =ND	Findings related to HL
30	Smylie et al. 2018 Canada	SD: Pre-post-design S: N = 47	Indigenous clients with or at high risk of CVD Aim: To test the effect of a customized, structured HL educational program addressing CVD medications.	The Canadian Expert Panel on Health S: Comprehensive Indigenous health service which provides primary health care, M: (2) Group. Three sequential educational sessions with an Indigenous nurse over 4–7 weeks.	1: Participant's health literacy practices were assessed by the intervention nurse Not described = ND	There was a non-significant increase in participants who spontaneously accessed any source of medication information. Participants were significantly more likely to be answering questions from other people regarding their medications between sessions 2 and 3 (T5) compared to between sessions 1 and 2 (T3) (p = 0.018)
31	Sugita et al. 2017 Japan	SD: a single-center, open-label, randomized controlled study S: N = 41 (IG: 21, CG: 20)	Patients hospitalized strictly for type 2 diabetes Aim: to examine the effect of a text message-based HL intervention to promote medication adherence	Nutbeam's definition S; University Hospital M: (4) remote, text message-based HL intervention to promote medication adherence, compared to text message reminders only	2: HL was measured using scales developed by Ishikawa et al.	No significant difference between groups was observed for the HL outcomes.
32	Swavely et al. 2013 United States	SD: A prospective pre-post evaluation design S: N = 106	Patients diagnosed with type 2 diabetes Aim: to evaluate the effectiveness of the LHL diabetes education program	Committee on Health Literacy, Institute of Medicine, 2004 S: From six primary care medical practices M: (3) Combi, the Low HL diabetes education programme: individualized and group diabetes education, 13 h of education over 12 weeks	ND: STOFHLA	At the completion of the program patients had significant improvements in diabetes knowledge (p < .001), self-efficacy (p < .001), and three domains of self-care including diet (p < .001), foot care (p < .001), and exercise (p < .001).
33	Tai et al. 2016 Iran	SD: A multisite, randomized, controlled, open, multi-arm, pre-post interventional trial S: N = 172 (IG: 23 + 68, CG: 19 + 62).	Older adults (>55 y) taking 2 or more Rx medications daily Aim: to assess the effectiveness of an educational intervention on prescription (Rx) label comprehension and functional HL (FHL)	Institute of Medicine 2004 S: Senior centers M: (1) Individual, a 10- minute one-one session in with education on the identification and understanding of all the critical elements of a sample Rx label	Short Test of Functional Health Literacy in Adults (STOFHLA)	Participants using redesigned label (n = 48) showed significant improvement in STOFHLA (29.8 ± 7.5–31.5 ± 5.7; P ¼ 0.011) scores, whereas intervention participants using current Rx label (n = 16) did not show significant improvement in STOFHLA (P = 0.215) scores.
34	Tavakoly Sany et al. 2019 Iran	SD: RCT study S: N = 80 (IG: 40, CG: 40)	Patients with heart failure (HF) Aim: (1) determine the level of HL among Iranian patients with HF and (2) examine the potential impact of educational interventions	Sørensen et al. 2012 S: A Teaching Hospital M: (2) Group, three educational workshops led by a cardiovascular disease specialist using the educational manual Caring for Your Heart	1: American TOFHLA	Significant changes in patients' health literacy, self efficacy and self-care (p < 0.05) were detected in the intervention compared to the control groups at post-intervention and 3-months follow-up.
35	Tavakoly Sany et al. 2020 Iran	SD: RCT design (with two parallel arms) S: 35 physicians and 240 patients (IG: 119, CG: 121)	Hypertensive patients Aim: to examine the effectiveness of communication skills training for physicians on the hypertension outcomes and the health literacy skills, self-efficacy and medication adherence for HBP patients	NO S: Primary health care centers M: (2) Group. Physicians in the intervention group received educational training to promote communication skills. Group Discussion (FGD) and 2 workshops (10 h per session). The control group: no training.	2: Chew's Screening Questions (CSQ)	A significant difference (p < 0.05) was found between participants (physicians and patients) in the intervention versus control groups at follow-up, and in change from baseline to follow-up in all scores including physician's communication skills, patient's HL skills, medication adherence, patients' self-efficacy, SBP and DBP.

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Table 2 (continued)

Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No	Setting (S)/ Mode of the intervention (M)	HL outcome: Primary = 1, Secondary = 2 Not described =ND	Findings related to HL
36 Wang et al. 2019 China	SD: four-arm cluster RCT,S: 799 (IG1: HL:200, IG2: Exercise group: 200, IG3: comprehensive group: 199, CG; 200)	Patients with diabetes Aim: to evaluate the effectiveness of HL and exercise-focused interventions on clinical outcomes	Nutbeam 2000	S: 35 clinics in 8 communities M: 1) Individual. One standard care (control) arm and three intervention arms receiving interventions focused on health literacy, exercise or both.	2: Chinese versions of Health Literacy Management Scale (HeLMS)	Both health literacy and exercise-focused interventions decreased A1c in diabetes patients. The significant improvements in A1c relative to the control arm remained even after a 1 year follow-up period post-intervention.
37 Wolf et al. 2014 United States	S: quasi-experimental, N = 486 (Carve-In (n = 214), Carve-Out (n = 272))	Patients with type 2 diabetes mellitus Aim: to compare the two implementation methods and best understand the advantages and challenges of each	NO	S: Six community health centers M: (1) Individual, a clinic-based approach that involved practice redesign [CARVE-IN]; or 2) an outsourced approach with a telephone-based diabetes educator for the same services [CARVE-OUT].	ND: Rapid Estimate of Adult Literacy in Medicine (REALM).	Carve-in patients with limited literacy had more contact with nurses (p = .01), better recalled the nurse speaking to them (p < 0.001) and setting action plans (p < 0.001), and rated the process as more helpful than those with adequate literacy (p = .03); the reverse was true in the carve-out arm.
Author, Country of origin, Year	Study design (SD) & Sample size (S:)	Type of chronic disease/ condition targeted	Definition of health literacy Yes/No (Reference)	Setting (S)/ Mode of the intervention (M)	HL outcome / Primary e= 1, Secondary = 2 Not described =ND	Findings related to HL
38 Zhang et al. 2019 China	SD: RCT design (+ qualitative methods) N = 1080 S: IG: 1080, CG: 588	Patients with hypertension Aim: to explore an innovative community-based hypertension self-management model and to evaluate its effects	NO	S: Community living M: (2) Group, six sessions, each lasting from one to one and a half hours weekly. The follow-up management sessions were conducted monthly (1 h). The intervention addressed health needs, whereas follow-up management involved sharing of self-management experiences in an interactive format.	The Health Literacy Management Scale	There was a significant difference in general health and health literacy after the intervention for the intervention patients group (P < .05). Furthermore, the proportion of health literacy was higher in the intervention group than in the control group (71.6% vs 59.6%).
39 Zullig et al. 2014 United States	S: Pilot study (pre/post) S: N = 23	Patients with Hyper tension, diabetes, and/or hyper-cholesterolemia & CVD risk factors Aim: to explore an innovative community-based hypertension self-management model and to evaluate its effects	NO	S: Hospital-based primary care clinics (out patients) M: (1) Individual. Information for each medication was put into individualized medication calendars with 5 topics.	The Rapid Estimate of Adult Literacy in Medicine (REALM) test.	Forty per cent had low health literacy. Patients showed changes in medication adherence and clinical outcomes at six months.

Health literacy (HL); functional HL (FHL); self management (SM); Mode: (1) individual education, (2) group education, (3) a combination of individual and group education, and (4) intervention primarily delivered by remote methods; high blood pressure (HBP), cardio vascular disease (CVD), Domains of healthcare (HC), disease prevention (DP), and health promotion (HP).

Table 3
HL definitions used in the included studies.

Definition Reference	Definition	Number of references
Institute of Medicine (2004)	The “capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (p. 32),	N = 4 (Kim et al. 2015, Kim et al. 2019, Lee et al., 2018, Swavely et al. 2014)
Sørensen et al. (2012)	“Health literacy is linked to literacy and entails people’s knowledge, motivation and competencies to access, understand, appraise and apply information to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain and improve quality of life during the life course.”	N = 4 (Knudsen et al. 2020, Muller et al., 2017, Seidling et al. 2020, Tavakoly Sany et al. 2019)
WHO (1998)	“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”	N = 4 (Moura et al. 2019, Huang et al. 2020, Hæsum et al. 2017, Korsbakke et al., 2016)
Nutbeam (2000)	The personal, cognitive and social skills which determine the ability of individuals to gain access to, understand, and use information to promote and maintain good health.’	N = 4 (Banbury et al., 2020, Lee et al., 2017, Sugita et al. 2017, Wang et al., 2019)
Ratzkan and Parker (2000)	The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (p. vi)	N = 2 (Kim et al., 2020, Negarandeh et al. 2013)
Kutner (2006)	To have below basic or basic health literacy, translates to limited capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions	N = 2 (Noureldin et al. 2012, Tai et al., 2016)
The Canadian Expert Panel on Health (Rootman and Gordon-El-Bihbety 2008)	The ability to access, understand, evaluate and communicate information as a way to promote, maintain and improve health in a variety of settings across the life-course (p.11)	N = 1 (Smylie et al. 2018)
Norman (2006, 2011)	Electronic health literacy is the ability to use this resource to access, understand, and use Internet-based health information for self-care.	N = 1 (Nokes et al. 2019)

self-management skills [48]. Furthermore, some of the interventions focused on building self-efficacy [36,58]. The content of the interventions targeted learning words and phrases and increasing knowledge [30, 60, 74], as well as problem-solving in diverse settings [47,62].

A broad variety of **educational approaches** were used in the identified interventions. Examples include lecturing and counselling approaches, booklets and standardized texts [35,44], tests [75], feed-back based approaches, images and videos, action and navigation plans, workshop discussions, roundtable conversations [30] and other interactive methods [29], mastery demonstrations, teach-back [49], and motivational and social support strategies [36]. Multiple approaches were combined in many interventions, and they were performed face-to-face, digitally and/or by telephone. The approaches were varied and included individually tailored programmes [35], standardized educational programmes [75], or a mixture of these [59].

The **mode** of the interventions can be classified into four categories: individual focus (13 interventions); group interventions, with between one and 12 meetings (12 interventions); combined individual and group focus (4 interventions); and mostly remote (individual), with contact with subjects happening online or by telephone (10 interventions). One of the interventions targeted health care personnel (HCP) [61], with physicians in the intervention group receiving educational training to promote their communication skills, in relation to the hypertension outcomes and the health literacy skills, self-efficacy and medication adherence in patients with high blood pressure (see Table 2). The time frame of delivery ranged from one session [58] to intervention programmes covering several weeks or months of follow-up [47,75]. However, most interventions lasted for weeks or months, combining different approaches such as teaching, testing and telephone/digital consultations or messages. The length of the sessions also varied, ranging from 5 to 10 min [46] (e.g. shorter information and tests) to 2 h [47] (workshops and education).

Many of the interventions included **technical equipment and other material** for patients to use. For instance, smart devices, various tablets and mobile apps were used for educational purposes, monitoring and self-reporting [43]. In addition, peripheral equipment such as a weight scales and blood pressure, heart rate and glucose monitors were handed out individually to patients [31].

The interventions were delivered by a wide variety of **health care providers** (i.e. physicians, pharmacists, nutritionists, nurses, medical consultants, occupational therapists, community and social health

workers, physiotherapists, and health educators). Often the health care providers were specialists in the target area of the interventions, such as diabetes, oncology, mental health, community health, and cardiovascular diseases [38,52]. However, it seemed like the goal and content of the interventions reflected the competence profile of the providers. For instance, pharmacists provided interventions addressing medical adherence [41,44], and nurses provided interventions addressing broader self-management [52].

3.3. Quality appraisal

Among the included studies, 30 were appraised using the ROB2 tool (26 RCT studies and 4 quasi-randomized controlled studies). The overall risk of bias was evaluated as being “low” in only two studies [45,60] (6.7%); there was “some concern” about bias in eight studies (26.7%) and “high risk” of bias in 20 (66.7%) studies. Typical areas of concern included domain one (Randomization; 50%), domain two (Deviations from intended intervention, 83%), and domain five (Bias in selection of the reported outcome; 67%) (see Figs. 2, 3 Supplementary file 2). Hence, it appears that the majority of the included studies either raise some doubt about their results or have little confidence in them. The results of the ROB assessment are summarized in Fig. 2 and Fig. 3 Supplementary file 2 (ROB 2 graph: review authors’ judgments about each ROB item presented as percentages across all included studies).

Nine studies, seven pre/post studies [35–41] and the two non-randomized quasi experimental studies [29,31] were assessed with the Joanna Briggs Institute Appraisal for Quasi Experimental Studies (Table 4). They scored from five to eight “yesses” on a total of nine questions, indicating an overall moderate risk of bias (our judgement). Only one study scored eight out of nine YES, only lacking a control group [38]. Few studies included a control group, and there were some uncertainties about whether the outcomes were measured using a reliable tool/measurement and whether proper statistical methods were used.

3.4. Outcome measures

HL was presented as the primary outcome in 15 studies; in most studies, HL was a secondary outcome or the ranking was not described (see Table 2). There was significant heterogeneity in the use of outcome measures identified through this review, with a total of 23 different measures (see Table 5). Most commonly included were functional HL

Study	Risk of bias domains					Overall
	D1	D2	D3	D4	D5	
Bahrami 2019	-	X	+	+	-	X
Carroll et. al. 2019	+	-	+	X	-	X
DeWalt 2012	-	-	+	-	+	-
dos Santos 2019	X	-	X	-	-	X
Huang 2018	+	+	+	+	-	-
Hæsum 2016	+	-	+	-	+	-
Hæsum 2017	-	X	X	X	+	X
Kim 2014	-	X	-	-	+	X
Kim 2019	+	X	X	X	-	X
Kim. 2020	-	-	+	+	-	-
Koonce 2015	-	X	X	X	X	X
Lee 2017	+	+	+	+	+	+
Lee 2018	+	-	X	+	-	X
Mudiyanselage,2019	-	-	+	-	+	-
Muller, 2017	+	+	+	+	-	-
Negarandeh, 2012	+	+	+	X	-	X
Nokes, 2019	+	X	X	-	-	X
Noureldin, 2012	+	-	+	-	X	X
Prabsangob,2019	+	-	+	+	-	-
Rastegar et. al. 2020	+	-	+	-	-	X
Rust 2015	-	-	-	X	-	X
Salisbury 2016	+	X	+	-	+	X
Seidling	X	-	+	X	-	X
Sugita, 2017	+	-	+	X	-	X
Tai 2016	-	-	X	-	-	X
Tavakoly Sany 2019	-	+	+	+	+	+
Tavakoly Sany, 2020	+	X	+	+	-	-
Wang 2019	X	-	-	+	-	X
Wolf 2013	-	X	X	X	-	X
Zhang 2019	-	-	+	X	-	X

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.




Judgement
 High
 Some concerns
 Low

Fig. 2. Within studies risk of bias assessment (RoB-2) for RCTs on five criteria and overall.

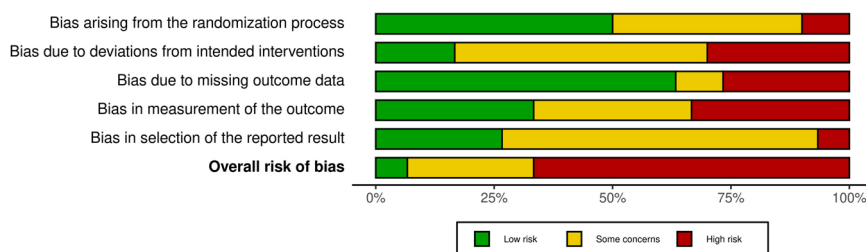


Fig. 3. ROB 2 graph summary plot: review authors' judgments about each ROB item presented as percentages across all included studies.

measures such as the Test of Functional Health Literacy in Adults (TOFHLA) (used in seven studies) [40, 42, 43, 50, 54, 58–60] and the Short TOFHLA (S-TOFHLA) (two studies) [40,46], the Rapid Estimate of Adult Literacy in Medicine (REALM) (four studies) [33, 36, 41, 50] and the Chew's Subjective Literacy Screening (with 3 or 4 questions; three studies) [51, 61, 66]. Some studies also used more comprehensive measures, such as the Health Literacy Questionnaire (HLQ) in three studies [29, 31, 76], the E-Heals in three studies [32, 38, 67], and the Health Literacy Survey European (HIS-EU Q47) in one study [74]. Six studies used disease-specific measures related to diabetes [30, 53, 56], cancer [48], breast cancer [74] and high blood pressure [48]. In addition, five studies used national adapted measures representing Korea [45,49], China [57,62], and Iran [65]. Some studies did not apply a standard measure to assess HL; for example, in one study, the participants' HL practices were assessed by a nurse [39], another used a prescription label comprehension survey and a pillbox test as a proxy for functional HL [44], while a third study used knowledge about the CVD medications assessed before and after each session [35]. A self-management measure (the Health Education Impact Questionnaire) was defined as an HL tool in two studies [29,52]. Only two studies used more than one measure of HL [46,50].

3.5. Effect of the interventions

A statistically significant effect on HL post-intervention was reported in 28 (71.8%) of the interventions; 21 of these studies measured functional HL, while seven used more comprehensive measures (See Table 2). Eight of the 13 studies with individual focus reported some effect on HL post-intervention [33, 35, 44, 46, 51, 63, 64, 69]. However, three of the studies with individual focus claiming to be HL interventions (but with no apparent HL measure) reported effects related to other outcomes (i.e. medication adherence, patient activation and self-care behaviours). They did not measure HL post-intervention but divided participants into low/high HL groups [41, 49, 59]. Ten of twelve studies reported effects on HL in the group interventions [30, 32, 34, 39, 45, 54, 60–62, 65]. Three of five reported an effect on HL in the combination mode interventions [37, 48, 68], while five of the nine interventions with mostly remote modes (individual web and telephone) reported a significant effect [31, 42, 52, 53, 67]. Several studies used the HL measures as a classification to recognize participants with limited HL (for example, Tavakoly Sany et al. [60], dos Santos et al. [30] and Banbury et al. [29], thereby only measuring HL once, making it impossible to use as an effect measure.

We tried to pool the data statistically in several different ways. However, there were not enough studies with similar outcome measures, similar chronic diseases or similar modes or intervention content to consider quantitative analysis (meta-analysis or statistical pooling) of data; therefore, a narrative analysis was performed.

The three promising interventions that scored low risk of bias were further explored [38, 44, 60] to see whether they had commonalities regarding theory base, intervention content, settings, targeted disease, or health literacy measures used. This examination showed the same variety as our overall assessment of the interventions. Only the study by Tavakoly-Sany reported a theoretical underpinning using Sørensen's HL

model [73]. There were different patient groups (heart failure [60], cancer survivors [38] and older adults with diabetes [61]). There were no similar HL measures among the studies, using eHeals [38], TOFHLA [60] and the Korean Health Literacy Assessment Tool [45]. There were two group modes and one remote [38], three different clinical settings and various interventional content. However, regarding the effect of the interventions, the two group-based interventions [45,60] showed a significant effect on self-efficacy and self-care/self-management in addition to health literacy.

4. Discussion and conclusion

4.1. Discussion

The current review extends previous reviews on HL interventions by more thoroughly investigating the evidence of HL interventions by focusing on both conceptual and methodological aspects across and within the interventions. This review has looked at the theoretical perspectives, the content, and the effectiveness of HL interventions for patients with chronic conditions and is, to the best of our knowledge, the first review to do so. Our conclusion after performing this review is that it remains unclear how HL is understood and practised in interventions. The questions become how can the research community replicate efficacy studies and how can knowledge from meta-studies inform clinical practice, i.e. support evidence-based practice? Health care practitioners need to know how to develop and test interventions, i.e. sticking to the processes that have been shown to have an effect.

First, the results of the selected studies were generally in favour of the intervention, and 72% of the studies reported a significant HL effect; however, most measured functional HL. The potential value of HL interventions in a chronic care context is supported by the consistent (i.e., no variance in the direction of the effect) significant positive outcomes reported across studies, despite considerable heterogeneity in the magnitude of the effect. A positive trend towards the effect of HL interventions is also found in disease-specific reviews in chronic conditions such as COPD [77], diabetes [78] and heart failure [79].

However, it should be noted that 37 of the 39 included studies were at risk of bias, with 23 judged at overall high risk. This may impact our ability to draw reliable conclusions from the included studies. Low study quality has also been underscored in other systematic reviews on HL [80]. This raises important concerns about the design of HL intervention research and for evidence-based practice in this field.

It is important to note that a major part of the studies included (21/39) in this review failed to provide a conceptual definition of HL and that the definitions reported broad varieties. The heterogeneity of the included HL definitions is not surprising, given that there is still a lack of a consensus on how to define HL [81,82]. Some studies defined HL in a simple way as "the ability to obtain, process, and understand basic health information and services", thereby failing to recognize the multidimensional nature of HL that goes beyond these abilities. Some definitions also have a broader context, including motivation and quality of life [73].

Despite including broad definitions of HL, some of the studies only focused on essential reading and numeracy skills in the measured

Table 4
The Joanna Briggs Institute critical appraisal of study quality (Quasi-Experimental Studies).

	1: Is it clear in the study what is the 'cause' and what is the 'effect'?	2: Were the participants included in any comparisons similar?	3: Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	4: Was there a control group?	5: Were there multiple measurements of the outcome, both pre and post-intervention/exposure?	6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	7. Were the outcomes of participants included in any comparisons measured in the same way?	8. Were outcomes measured in a reliable way?	9. Was appropriate statistical analysis used?
Banbury et al. (2020)	YES	NO	UNCLEAR	YES	YES	UNCLEAR	YES	YES	NO
Crengle et al. (2018)	YES	YES	NO	NO	YES	YES	YES	YES	YES
Dworkin et al. (2019)	YES	NO	NO	NO	YES	YES	NO	YES	YES
Han et al. (2018)	YES	YES	NO	NO	YES	YES	YES	UNCLEAR	UNCLEAR
Knudsen et al. (2020)	YES	YES	UNCLEAR	NO	YES	NO	YES	YES	YES
Nahm et al. (2019)	YES	YES	YES	NO	YES	YES	YES	YES	YES
Smylie et al., (2018)	YES	YES	NO	NO	YES	YES	NO	UNCLEAR	YES
Swavely et al. (2013)	YES	YES	YES	NO	YES	NO	YES	YES	YES
Zullig et al. (2014)	YES	YES	NO	NO	YES	YES	YES	UNCLEAR	UNCLEAR

outcome [42, 43, 53], thereby showing a lack of consistency between the definitional theoretical underpinnings the intervention provided and the selected outcome measures. An important question lies in how to evaluate the effectiveness of the intervention process if it is not clear what the interventions are supposed to accomplish. This has implications for the examination of the hypothesis on causality. Our findings may also indicate that the choice of instruments is rather pragmatic, or at least that there is a lack of clarity as to how the causal relationship between the HL interventions' content and the intended outcomes are understood.

An essential finding of this review, in line with Nutbeam and Muscat [83], was the lack of studies using a comprehensive HL outcome measure that included higher-order and transferable HL skills. It is a paradox that many of the studies in this review did not include measures capable of or suitable for measuring all aspects of the multidimensional HL skills targeted in the interventions. This finding is supported by a recent systematic review on HL interventions [84] and seems to be a concern within HL research. Further research is needed to understand better what HL interventions entails.

None of the interventions in the review focused on organizational HL (OHL), and only one intervention focused directly on increasing HCP's HL skills [61] (even if several interventions provided some HCP education [85]). This lack of focus on OHL is also underscored in a recent report by Nutbeam [4]. Actually, a range of models and practical strategies have been described to help create health-literate organizations that reduce and simplify the demands of people who engage with those organizations and health professionals [86,87]. A recent review [88] found that the dominant factors influencing implementation of OHL interventions included staff knowledge of OHL, executive leadership with HL expertise, shared responsibility and a systematic approach to implementation. Information regarding these factors is not given in the studies included in the current review and may impact on quality appraisals. Hence, future HL research needs to embrace a broader system approach in the development of interventions for people with chronic conditions to become more relevant for clinical practice [89]. However, our lack of findings on OHL interventions may be in part due to the search strategy applied, even if the search included the possibility to include up to four words between health and literacy (Supplementary file 1).

A surprising finding in the current review is that the use of modern technology (e.g. web and mobile apps) as a primary mode was remarkably limited (N = 8/39, 20.5%). Nevertheless, these studies were all conducted during the last five years. This low number contrasts with the systematic review of HL interventions in the EU, where the web

mode was dominant [16]. Five of the nine studies using a mostly remote intervention reported that websites, portal e-messages or interactive software were not more effective in improving HL [31, 38, 42, 55, 56]. There may be some challenges using eHealth interventions in a chronic care context for individuals with varying degrees of HL; barriers to accessing online health information can include the availability and readability of content and the usability of eHealth services. Only two e-HL interventions [38,67] assessed the effect of the interventions with a tailored HL measure, the e-Heals, which measures an individual's perceived skill at finding and using online health information [90].

A recent systematic review on people with selected NCDs living in low-to-middle income countries also found a low percentage of web interventions [5]. The authors hypothesized that low HL might reflect socio-economic hardship in these countries, which limited access to technology-based interventions. Most of our studies were from middle-to high-income countries, although some had low income as an inclusion criterion [32].

Our review includes studies from 15 countries, comprising over 10,000 participants with chronic conditions. Most of the included studies originate from the USA; this is in line with other systematic reviews on HL [84,91]; there is a noticeable lack of African studies and very few from the Middle East and Eastern Europe. The included studies covered a variety of chronic diseases. Most interventions had a diagnosis-specific focus, and only four interventions targeted more than one chronic disease [29, 41, 44, 52]. The main groups are interventions for patients with diabetes and cardiovascular diseases (including high blood pressure). HL is, in part, culturally conditioned. For knowledge to be generalized, studies need to be included from heterogeneous medical and cultural contexts. We hypothesize that studies from high-income countries with a highly educated population may not easily be transferred to low-income countries with a low-educated population.

Based on this review, we will point to some needs for future HL intervention research. Studies must be consistent regarding the skills and tasks that interventions focus on [83]. Also, more interventions need to target more than functional HL, for example, focusing on interactive and critical HL. Furthermore, we suggest that HL needs to be the primary outcome measure. Also, the HL measure must be in line with the applied intervention; for instance, if the intervention targets functional HL, a functional measure needs to be implemented, while if the intervention is more complex or targets broader skills and tasks such as those related to interactive or critical aspects of HL, more comprehensive measures need to be included. The distinction between the concepts of HL and self-management are unclear, and self-management interventions may be understood as HL interventions, even if they clearly do not include

Table 5
Health literacy instruments.

Health literacy measures	Studies (n)	Study citations
Functional HL measures		
Chew Subjective Literacy Screening		
3 questions	2	Koonce et al. (2015), Rust et al. (2015)
4 questions	1	Tavakoly Sany, (2020)
Rapid Estimate of Adult Literacy in Medicine (REALM)	4	Dworkin et al. (2019), Kim et al. (2020), Wolf (2012), Zullig (2014)
Newest Vital Sign (NVS)	1	Hae-Ra et al. (2018)
Test of Functional Health Literacy in Adults (TOFHLA)	6	DeWalt et al. (2012), Hæsum et al. (2017), Kim et al. (2020), Negarandeh et al. (2013), Noureldin et al. (2012), Tavakoly Sany et al. (2019)
TOFHLA SHORT VERSION (STOFHLA)	2	Tai et al. (2016), Swavely et al. (2013)
Comprehensive HL measures		
Health Literacy Questionnaire (HLQ)	3	Banbury et al. (2020), Knudsen et al. (2020), Seidling et al. (2020)
HLS-EU Q47	1	Huang et al. (2018)
HLS-EU Q 16	1	Huang et al. (2018)
e-Heals	3	Nahm et al. (2019), Nokes et al. (2019), Salisbury et al. (2016)
Nationally adapted		
Iranian Health Literacy Questionnaire (IHLQ)	1	Rastegar et al. (2020)
Korean Functional Health Literacy Test (KFHLT)	1	Kim et al. (2019)
Korean Health Literacy Assessment Tool	1	Lee et al. (2017)
Chinese versions of HL Management Scale (HeLMS)	1	Wang et al. (2019)
Chinese Health Literacy Scale (CHLSH)	1	Zhang et al. (2019)
Illness specific:		
Questionário de Atividades para Autocuidado com Diabetes (QAD)	1	Moura (2019)
Diabetes knowledge, patient enablement, and attitude	1	Muller (2017)
HL measured using scales developed by Ishikawa et al. (diabetes)	1	Sugita et al. (2017)
The HBP health literacy scale	1	Kim KB 2014
Cancer Health Literacy Test	1	Bahrami et al. 2019
Others		
Name of medicine/knowledge	1	Crengle et al. 2018
Participants' HL practices assessed by the nurse	1	Smylie et al. (2018)
Pillbox Fill Test	1	Lee et al. (2018)
An unnamed measure of HL	1	Prabsangob et al. (2019)

CSQ: Chew's Subjective Literacy Screening Questions REALM: Rapid Estimate of Adult Literacy in Medicine, NVS: Newest Vital Sign, TOFHLA: Test of Functional Health Literacy in Adults. HLQ: Health Literacy Questionnaire V, HeIQ: Health Education Impact Questionnaire, QAD: Questionário de Atividades para Autocuidado com Diabetes, KFHLT: Korean Functional Health Literacy Test, HBP: The HBP health literacy scale (2 domains—print literacy and functional health literacy for High Blood Pressure), e-HEALS: eHealth Literacy Scale, HL Scale developed by Ishikawa et al.: functional HL (five items), communicative HL (five items), and critical HL (four items). Health Literacy Survey European Questionnaire (HLS-EU).

the concepts of obtaining, processing, and understanding health information. Finally, to strengthen HL intervention research, it may be valuable to investigate different HL practices to find the most appropriate.

This review has several strengths and some limitations. We used a broad and thorough search strategy yielding 3882 unique citations and applied a rigorous and structured selection and extraction procedure form. In addition, the qualitative analyses of the texts describing the interventions provide a deeper understanding of their content, theoretical foundation, and pedagogical strategies. The review group consisted of 14 researchers, indicating potential problems with interrater reliability. However, a core group of four reviewers safeguarded and calibrated all processes. Also, to reduce bias, four reviewers assessed each intervention individually and then used Nvivo to identify relevant extractions together. Finally, there may be technical limitations due to study selection. By restricting the included studies to those that explicitly presented an HL intervention, if not a precise HL measure, we may have missed other studies that could be advantageous to patients with chronic conditions and low HL. In addition, we restricted our search to full peer-reviewed quantitative papers published in English and Scandinavian languages, but there may be qualitative studies or studies in other languages that could contribute to the review questions.

4.2. Conclusion

HL appears to have the potential to be an effective means of improving health literacy and other health outcomes in people with chronic conditions. However, in our study this conclusion is threatened

by the low methodological quality of the included studies. Furthermore, if HL intervention research aims to become a foundation for evidence-based practice in chronic conditions, the research needs more theoretical and methodological consistency and more tailored and comprehensive measures to capture the complexity of the interventions. An increased focus on the content of interventions and on measuring their effect using appropriate measures is needed.

4.3. Practice implications

Optimising HL has been pointed to as a possible key to decreasing the global burden of chronic conditions. Hence, health care professionals need to know how to develop and test such interventions. The interventions in this review show the potential to make a positive impact on a broad range of health issues, but health literacy interventions are not easy to define. Developing a more common understanding of what HL interventions are supposed to be, associated measurements, and the mechanisms of effects is necessary. To produce efficient HL research for evidence-based practice it is necessary to develop a more common understanding of what HL interventions should entail, associated measurements and the mechanisms of effects.

CRediT authorship contribution statement

Marie H Larsen: Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft, Writing – review & editing, Visualization, Project administration and Supervision. **Anne Marit Mengshoel:** Conceptualization, Methodology, Formal analysis, Writing

– original draft, review. **Marit H. Andersen:** Conceptualization, Methodology, Formal analysis, Writing – review and editing. **Christine R Borge:** Conceptualization, Methodology, Writing review & editing, Formal analysis. **Birgitte Ahlsen:** Methodology, Investigation, Writing – review & editing. **Kari Gire Dahl:** Methodology, Investigation, Writing – review & editing. **Hedda Eik:** Methodology, Investigation, Writing – review & editing. **Heidi Holmen:** Methodology, Investigation, Writing – review & editing. **Anners Lerdal:** Methodology, Investigation, Writing – review & editing. **Kari L. Mariussen:** Investigation, Formal analysis, Writing – review & editing. **Lisbeth Thoresen:** Methodology, Investigation, Writing – review & editing. **Merete K Tschamper:** Methodology, Investigation, Writing – review & editing. **Kristin H. Urstad:** Methodology, Investigation, Writing – review & editing. **Tone K Vidnes:** Methodology, Investigation, Writing – review & editing. **Astrid K. Wahl:** Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft, review, Project administration and supervision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.pec.2022.05.008](https://doi.org/10.1016/j.pec.2022.05.008).

References

- Nutbeam D, Muscat DM. Health promotion glossary 2021. *Health Promot Int* 2021.
- Nutbeam D. The evolving concept of health literacy. *Soc Sci Med* 2008;67(12):2072–8.
- Paasche-Orlow MK, Wolf MS. The causal pathways linking health literacy to health outcomes. *Am J Health Behav* 2007;31.
- Nutbeam D, Lloyd JE. Understanding and responding to health literacy as a social determinant of health. *Ann Rev Public Health* 2021;42(1):159–73.
- Heine M, Lategan F, Erasmus M, Lombaard CM, Mc Carthy N, Olivier J, et al. Health education interventions to promote health literacy in adults with selected non-communicable diseases living in low-to-middle income countries: a systematic review and meta-analysis. *J Eval Clin Pr* 2021. Mar22.
- Dias S, Gama A, Maia AC, Marques MJ, Campos Fernandes A, Goes AR, et al. Migrant communities at the center in co-design of health literacy-based innovative solutions for non-communicable diseases prevention and risk reduction: application of the optimising health literacy and access (Ophelia) process. *Front Public Health* 2021;9(616).
- Hori S, Fujimoto S, Sugita S, Kobayashi M, Komukai K. The effects of Intervention for the health literacy of patients: a systematic review of randomized controlled trials. *J Jpn Prim Care Assoc* 2018;41(3):100–9.
- Mackey LM, Doody C, Werner EL, Fullen B. Self-management skills in chronic disease management: what role does health literacy have? *Med Decis Mak* 2016;36(6):741–59.
- Nutbeam DMD. Advancing health literacy interventions. *Stud Health Technol Inf* 2020;269:115–27.
- Aaby A, Friis K, Christensen B, Maindal HT. Health literacy among people in cardiac rehabilitation: associations with participation and health-related quality of life in the heart skills study in Denmark. *Int J Environ Res Public Health* 2020;17(2):443.
- Al Sayah F, Majumdar SR, Williams B, Robertson S, Johnson JA. Health literacy and health outcomes in diabetes: a systematic review. *J Gen Intern Med* 2013;28(3):444–52.
- Brainard J, Wilsher SH, Salter C, Loke YK. Methodological review: quality of randomized controlled trials in health literacy. *BMC Health Serv Res* 2016;16(1):246.
- Altin SV, Finke I, Kautz-Freimuth S. The evolution of health literacy assessment tools: a systematic review. *BMC Public Health* 2014;14(14):1207.
- Taggart J, Williams A, Dennis S, Newall A, Shortus T, Zwar N. A systematic review of interventions in primary care to improve health literacy for chronic disease behavioral risk factors. *BMC Fam Pract* 2012;13(13):49.
- Kiechle ES, Bailey SC, Hedlund LA, Viera AJ, Sheridan SL. Different measures, different outcomes? a systematic review of performance-based versus self-reported measures of health literacy and numeracy. *J Gen Intern Med* 2015;30(10):1538–46.
- Visscher BB, Steunenberg B, Heijmans M, Hofstede JM, Devillé W, van der Heide I, et al. Evidence on the effectiveness of health literacy interventions in the EU: a systematic review. *BMC Public Health* 2018;18(1):1414.
- Shum J, Poureslami I, Wiebe D, Doyle-Waters MM, Nimmon L, FitzGerald JM. Airway diseases and health literacy (HL) measurement tools: a systematic review to inform respiratory research and practice. *Patient Educ Couns* 2018;101(4):596–618.
- Fernández-González L, Bravo-Valenzuela P. Effective interventions to improve the health literacy of cancer patients. *Ecancelmedicallscience* 2019;13:966.
- Peltzer S, Hellstern M, Genske A, Jünger S, Woopen C, Albus C. Health literacy in persons at risk of and patients with coronary heart disease: a systematic review. *Soc Sci Med* 2020;245:112711.
- Taylor DM, Fraser S, Dudley C, Oniscu GC, Tomson C, Ravanan R, et al. Health literacy and patient outcomes in chronic kidney disease: a systematic review. *Nephrol Dial Transpl* 2018;33(9):1545–58.
- Malloy-Weir LJ, Charles C, Gafni A, Entwistle VA. Empirical relationships between health literacy and treatment decision making: A scoping review of the literature. *Patient Educ Couns* 2015;98(3):296–309.
- Pleasant A. Advancing health literacy measurement: a pathway to better health and health system performance. *J Health Commun* 2014;19:1481–96.
- Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: the PRISMA statement. *PLoS Med* 2009;6(7):e1000097.
- Hernandez L, Landi S. Institute of medicine (US), roundtable on health literacy. Promoting Health Literacy to Encourage Prevention and Wellness: Workshop Summary. Washington, DC: National Academies Press; 2011. p. 101.
- McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS peer review of electronic search strategies: 2015 guideline statement. *J Clin Epidemiol* 2016;75:40–6.
- Jackson K, Bazeley P. Qualitative data analysis with NVivo. Sage; 2019.
- Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ* 2019;366:14898.
- Tufanaru C, Aromataris E, Campbell J, Hopp L, Chapter 3: Systematic reviews of effectiveness. In: Aromataris E, ed. Joanna Briggs Institute Reviewer's Manual: The Joanna Briggs Institute, 2017. Available from <https://reviewersmanual.joannabriggs.org/> (Accessed March 2, 2021).
- Banbury A, Nancarrow S, Dart J, Gray L, Dodson S, Osborne R, et al. Adding value to remote monitoring: co-design of a health literacy intervention for older people with chronic disease delivered by telehealth - the telehealth literacy project. *Patient Educ Couns* 2020;103(3):597–606.
- Moura NDS, Lopes BB, Teixeira JJD, Oriá MOB, Vieira NFC, Guedes MVC. Literacy in health and self-care in people with type 2 diabetes mellitus. *Rev Bras Enferm* 2019;72(3):700–6.
- Knudsen MV, Petersen AK, Angel S, Hjortdal VE, Maindal HT, Laustsen S. Telerehabilitation and hospital-based cardiac rehabilitation are comparable in increasing patient activation and health literacy: a pilot study. *Eur J Cardiovasc Nurs* 2020;19(5):376–85.
- Nokes KM, Reyes DM. Do brief educational sessions increase electronic health literacy of low-income persons living with HIV/AIDS? *CIN Comput Inform Nurs* 2019;37(6):315–20.
- Wolf MS, Seligman H, Davis TC, Fleming DA, Curtis LM, Pandit AU, et al. Clinic-based versus outsourced implementation of a diabetes health literacy intervention. *J Gen Intern Med* 2014;29(1):59–67.
- Prabsangob KS, Kumar R, Anwar RF. Effectiveness of self-help group program for the management of type-2 diabetes patients in rural Thailand. *Pak J Nutr* 2019;18:141–5.
- Crengle S, Luke JN, Lambert M, Smylie JK, Reid S, Harré-Hindmarsh J, et al. Effect of a health literacy intervention trial on knowledge about cardiovascular disease medications among Indigenous peoples in Australia, Canada and New Zealand. *BMJ Open* 2018;8(1):e18569.
- Dworkin MS, Lee S, Chakraborty A, Monahan C, Hightow-Weidman L, Garofalo R, et al. Acceptability, feasibility, and preliminary efficacy of a theory-based relational embodied conversational agent mobile phone intervention to promote HIV medication adherence in young hivpositive African American MSM. *AIDS Educ Prev* 2019;31(1):17–37.
- Han H-R, Delva S, Greeno RV, Negoita S, Cajita M, Will W. A health literacy-focused intervention for latinos with hypertension. *Health Lit Res Pract* 2018;2(1):e21–5.
- Nahm ES, Miller K, McQuaige M, Corbitt N, Jaidar N, Rosenblatt P, et al. Testing the impact of a cancer survivorship patient engagement toolkit on selected health outcomes. *Oncol Nurs Forum* 2019;46(5):572–84.
- Smylie J, O'Brien K, Xavier CG, Anderson M, McKnight C, Downey B, et al. Primary care intervention to address cardiovascular disease medication health literacy among Indigenous peoples: Canadian results of a pre-post-design study. *Can J Public Health* 2018;109(1):117–27.
- Swavely D, Vorderstrasse A, Maldonado E, Eid S, Etchason J. Implementation and evaluation of a low health literacy and culturally sensitive diabetes education program. *J Health Qual* 2014;36(6):16–23.
- Zullig LL, McCant F, Melnyk SD, Danus S, Bosworth HB. A health literacy pilot intervention to improve medication adherence using Medication® technology. *Patient Educ Couns* 2014;95(2):288–91.
- Hæsum LKE, Ehlers LH, Hejlesen OK. The long-term effects of using telehomecare technology on functional health literacy: results from a randomized trial. *Public Health* 2017;150:43–50.
- Hæsum LKE, Ehlers L, Hejlesen OK. Interaction between functional health literacy and telehomecare: short-term effects from a randomized trial. *Nurs Health Sci* 2016;18(3):328–33.

- [44] Lee S, Khare MM, Olson HR, Chen AM, Law AV. The TEACH trial: tailored education to assist label comprehension and health literacy. *Res Soc Adm Pharm* 2018;14(9):839–45.
- [45] Lee SJ, Song M, Im EO. Effect of a health literacy–considered diabetes self-management program for older adults in South Korea. *Res Gerontol Nurs* 2017;10(5):215–25.
- [46] Tai BWB, Bae YH, LaRue CE, Law AV. Putting words into action: a simple focused education improves prescription label comprehension and functional health literacy. *J Am Pharm Assoc* 2016;56(2):145–52. e3.
- [47] Bahrami M, Behbahani MA. The effect of a health literacy promotion program on the level of health literacy and death anxiety in women with breast cancer. *Iran J Nurs Midwifery Res* 2019;24(4):286–90.
- [48] Kim KB, Han HR, Huh B, Nguyen SV, Lee H, Kim MT. The effect of a community-based selfhelp multimodal behavioral intervention in Korean American seniors with high blood pressure. *Am J Hypertens* 2014;27(9):1199–208.
- [49] Kim SH, Utz S. Effectiveness of a social media–based, health literacy–sensitive diabetes self-management intervention: a randomized controlled trial. *J Nurs Sch* 2019;51(6):661–9.
- [50] Kim MT, Kim KB, Ko J, Murry N, Xie B, Radhakrishnan K, et al. Health literacy and outcomes of a community-based self-help intervention: a case of Korean Americans with type 2 diabetes. *Nurs Res* 2020;69(3):210–8.
- [51] Koonce TY, Giuse NB, Kusnoor SV, Hurley S, Ye F. A personalized approach to deliver health care information to diabetic patients in community care clinics. *J Med Libr Assoc* 2015;103(3):123–30.
- [52] Bohingamu Mudiyansele S, Stevens J, Watts JJ, Toscano J, Kotowicz MA, Steinfert CL, et al. Personalised telehealth intervention for chronic disease management: a pilot randomised controlled trial. *J Telemed Telecare* 2019;25(6):343–52.
- [53] Muller I, Rowsell A, Stuart B, Hayter V, Little P, Ganahl K, et al. Effects on engagement and health literacy outcomes of web-based materials promoting physical activity in people with diabetes: an international randomized trial. *J Med Internet Res* 2017;19(1):e21.
- [54] Negarandeh R, Mahmoodi H, Noktehdan H, Heshmat R, Shakibazadeh E. Teach back and pictorial image educational strategies on knowledge about diabetes and medication/dietary 21 adherence among low health literate patients with type 2 diabetes. *Prim Care Diabetes* 2013;7(2):111–8.
- [55] Seidling HM, Mahler C, Strauß B, Weis A, Stützel M, Krisam J, et al. An electronic medication module to improve health literacy in patients with type 2 diabetes mellitus: pilot randomized controlled trial. *JMIR Form Res* 2020;4(4):e13746.
- [56] Sugita H, Shinohara R, Yokomichi H, Suzuki K, Yamagata Z. Effect of text messages to improve health literacy on medication adherence in patients with type 2 diabetes mellitus: a randomized controlled pilot trial. *Nagoya J Med Sci* 2017;79(3):313–21.
- [57] Wang L, Fang H, Xia Q, Liu X, Chen Y, Zhou P, et al. Health literacy and exercise-focused interventions on clinical measurements in Chinese diabetes patients: a cluster randomized controlled trial. *EclinicalMedicine* 2019;17:100211.
- [58] DeWalt DA, Schillinger D, Ruo B, Bibbins-Domingo K, Baker DW, Holmes GM, et al. Multisite randomized trial of a single-session versus multisession literacy-sensitive self-care intervention for patients with heart failure. *Circulation* 2012;125(23):2854–62.
- [59] Noureldin M, Plake KS, Morrow DG, Tu W, Wu J, Murray MD. Effect of health literacy on drug adherence in patients with heart failure. *Pharmacotherapy* 2012;32(9):819–26.
- [60] Tavakoly Sany SB, Peyman N, Zadehahmad Z, Ferns G, Doosti H. Effect of educational interventions on health literacy in patients with heart failure. *Int J Health Prom Educ* 2019;57(1):23–36.
- [61] Tavakoly Sany SB, Behzad F, Ferns G, Peyman N. Communication skills training for physicians improves health literacy and medical outcomes among patients with hypertension: a randomized controlled trial. *BMC Health Serv Res* 2020;20(1):60.
- [62] Zhang Y, Liu S, Sheng X, Lou J, Fu H, Sun X. Evaluation of a community-based hypertension self-management model with general practitioners. *Int J Health Plan Manag* 2019;34(3):960–74.
- [63] Bahrami M, Behbahani MA. The effect of a health literacy promotion program on the level of health literacy and death anxiety in women with breast cancer. *Iran J Nurs Midwifery Res* 2019;24(4):286–90.
- [64] Huang SC, Kuo SF, Tsai PS, Tsai CY, Chen SS, Lin CY, et al. Effectiveness of tailored rehabilitation education in improving the health literacy and health status of postoperative patients with breast cancer: a randomized controlled trial. *Cancer Nurs* 2020;43(1):E38–46.
- [65] Rastegar M, Mahmoodi Z, Saieeh SE, Sharifi N, Kabir K. The effect of health literacy counselling on self-care in women after mastectomy: a randomized clinical trial. *J Caring Sci* 2020;9(1):39–45.
- [66] Rust CF, Davis C, Moore MR. Medication adherence skills training for African-American breast cancer survivors: the effects on health literacy, medication adherence, and selfefficacy. *Soc Work Health Care* 2015;54(1):33–46.
- [67] Salisbury C, O’Cathain A, Edwards L, Thomas C, Gaunt D, Hollinghurst S, et al. Effectiveness of an integrated telehealth service for patients with depression: a pragmatic randomised controlled trial of a complex intervention. *Lancet Psychiatry* 2016;3(6):515–25.
- [68] Carroll JK, Tobin JN, Luque A, Farah S, Sanders M, Cassells A, et al. “Get Ready and Empowered About Treatment” (GREAT) Study: a pragmatic randomized controlled trial of activation in persons living with HIV. *J Gen Intern Med* 2019;34(9):1782–9.
- [69] Dworkin MS, Lee S, Chakraborty A, Monahan C, Hightow-Weidman L, Garofalo R, et al. Acceptability, feasibility, and preliminary efficacy of a theory-based relational embodied conversational agent mobile phone intervention to promote HIV medication adherence in young hivpositive African American MSM. *AIDS Educ Prev* 2019;31(1):17–37.
- [70] Nutbeam D. The evolving concept of health literacy. *Soc Sci Med* 2008;67(12):2072–8.
- [71] Nutbeam D. Health promotion glossary. *Health Promot Int* 1998;13.
- [72] Kindig D.A., Panzer A.M., Nielsen-Bohlman L., **Health literacy: a prescription to end confusion**, 2004.
- [73] Sørensen K, Broucke S, Fullam J. Health literacy and public health: a systematic review and integration of definitions and models. *BMC Public Health* 2012;12:80.
- [74] Huang SC, Kuo SF, Tsai PS, Tsai CY, Chen SS, Lin CY, et al. Effectiveness of tailored rehabilitation education in improving the health literacy and health status of postoperative patients with breast cancer: a randomized controlled trial. *Cancer Nurs* 2020;43(1):E38–46.
- [75] Carroll JK, Tobin JN, Luque A, Farah S, Sanders M, Cassells A, et al. “Get Ready and Empowered About Treatment” (GREAT) Study: a pragmatic randomized controlled trial of activation in persons living with HIV. *J Gen Intern Med* 2019;34(9):1782–9.
- [76] Seidling HM, Mahler C, Strauß B, Weis A, Stützel M, Krisam J, et al. An electronic medication module to improve health literacy in patients with type 2 diabetes mellitus: pilot randomized controlled trial. *JMIR Form Res* 2020;4(4):e13746.
- [77] Shnaigat M, Downie S, Hosseinzadeh H. Effectiveness of health literacy interventions on COPD self-management outcomes in outpatient settings: a systematic review. *COPD J Chronic Obstr Pulm Dis* 2021;18(3):367–73.
- [78] Kim SH, Lee A. Health-literacy-sensitive diabetes self-management interventions: a systematic review and meta-analysis. *World Evid Based Nurs* 2016;13(4):324–33.
- [79] Fabbri M, Murad MH, Wennberg AM, Turcano P, Erwin PJ, Alahadab F, et al. Health literacy and outcomes among patients with heart failure: a systematic review and metaanalysis. *JACC Heart Fail* 2020;8(6):451–60.
- [80] Walters R, Leslie SJ, Polson R, Cusack T, Gorely T. Establishing the efficacy of interventions to improve health literacy and health behaviours: a systematic review. *BMC Public Health* 2020;20(1):1040.
- [81] Liu C C, Wang D, Liu C, Jiang J, Wang X, Chen H, et al. What is the meaning of health literacy? A systematic review and qualitative synthesis. *Fam Med Community Health* 2020;8(2):e000351.
- [82] Malloy-Weir LJ, Charles C, Gafni A, Entwistle V. A review of health literacy: definitions, interpretations, and implications for policy initiatives. *J Public Health Policy* 2016;37(3):334–52.
- [83] Nutbeam D, Kickbusch I. Advancing health literacy: a global challenge for the 21st century [editorial]. *Health Promot Int* 2000;15.
- [84] Stormacq C, Wosinski J, Boillat E, Van den Broucke S. Effects of health literacy interventions on health-related outcomes in socioeconomically disadvantaged adults living in the community: a systematic review. *JBIC Evid Synth* 2020;18(7):1389–469.
- [85] Pleasant A, McKinney J. Coming to consensus on health literacy measurement: an online discussion and consensus-gauging process. *Nurs Outlook* 2011;59(2):95–106.
- [86] Trezona A, Dodson S, Osborne RH. Development of the Organisational Health Literacy Responsiveness (Org-HLR) self-assessment tool and process. *BMC Health Serv Res* 2018;18(1):694.
- [87] Brach C, Keller D, Hernandez LM, Baur C, Parker R, Dreyer B, et al. Ten attributes of health literate health care organizations. *NAM Perspect* 2012.
- [88] Meggetto E, Kent F, Ward B, Keleher H. Factors influencing implementation of organizational health literacy: a realist review. *J Health Organ Manag J Health Organ Manag* 2020.
- [89] Koh HK, Baur C, Brach C, Harris LM, Rowden JN. Toward a systems approach to health literacy research. *J Health Commun* 2013;18(1):1–5.
- [90] Norman CD, Skinner HA. eHEALS: the ehealth literacy scale. *J Med Internet Res* 2006;8(4):e27.
- [91] Chesser AK, Keene Woods N, Smothers K, Rogers N. Health literacy and older adults: a systematic review. *Gerontol Geriatr Med* 2016;2. 2333721416630492-2333721416630492.