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Health literacy in people with Venous Leg Ulcers: A protocol for scoping review

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**Health literacy in people with Venous Leg Ulcers:
A protocol for scoping review**

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Health literacy in people with Venous Leg Ulcers: A protocol for scoping review

Abstract

Introduction: Chronic venous leg ulcer (VLU) healing is a complex clinical problem. It requires intervention from skilled, costly, multidisciplinary wound-care teams, working with patients to manage their care. Compression therapy has been shown to help heal venous ulcers and to reduce recurrence, with some evidence suggesting the value of exercise as well. These activities require health education and health literacy (HL) as patients must process, understand and consistently apply health information for successful self-management. Research suggests that those most vulnerable to VLUs also tend to have limited HL, but there have been no reviews examining the state of HL in patients with previous or active VLUs. This scoping review (ScR) aims to develop a research strategy to scope what HL interventions exist for people with VLUs.

Methods and analysis: We will use Preferred Reporting Items for Systematic Reviews and Meta-Analyses Scoping Review guidelines and the Levac methodology framework to explore eligible papers that examine the effect of HL on their exercise and compression adherence. Electronic databases will be searched (MEDLINE, EMBASE, the Cochrane Library, PsycInfo and Health, OpenGray), examining for all papers on these subjects published between 2000 and 2020. All studies describing compression and or exercise during VLU management will be included. Study characteristics will be recorded; qualitative data will be extracted and evaluated. Quantitative data will be extracted and summarized.

Ethics and dissemination: We will disseminate results through peer-reviewed publications. We will use data (i.e., journal articles) from publicly available platforms; so this study does not require ethical review. The consultation step will be carried out with patients, carers and health professionals as part of an established wound consumer group.

Keywords: Venous Leg Ulcers; Health Literacy; Health Education; Compression; Compression Adherence

Article summary

Strengths and limitations of this study

- This scoping review protocol is the first to focus on the role of consumers' health literacy in venous leg ulcer management.
- In order to ensure a systematic approach to searching, screening and reporting, we utilise the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews tool, the most current guidance on conducting scoping reviews.
- We have included a comprehensive search strategy and data extraction template.
- The studies included in the review will be appraised for quality.
- Studies published outside of the indicated databases may be missed.

79 INTRODUCTION

80 Venous leg ulcers (VLUs) are chronic skin ulcers mainly affecting the gaiter area, most
81 often caused by continuous venous hypertension or chronic venous insufficiency.(1)
82 VLUs are a common health condition, affecting approximately 1-3% of people globally.
83 (2-4) This is often due to persistent high blood pressure in varicose veins.(5, 6) The
84 prevalence of VLU increases with age, doubling among those aged over 65 years.(7)
85 People with VLU often have various other comorbidities, including arterial hypertension,
86 obesity, non-insulin dependent diabetes and dyslipidaemia.(8) VLU healing, defined as
87 complete wound re-epithelization,(9) is often slow. The chance of recurrence of a healed
88 VLU is high.(10, 11) The cycle of healing and frequent recurrent episodes has significant
89 economic impact (4, 12-15) and severely affects VLU patients' health and wellbeing,
90 including that of their families.(16-18) Despite advances in treatments, sustained healing
91 of VLU continues to be an ongoing problem for patients, health services, and health
92 systems.(19)

93 Current best practice recommendation for people with active VLU is the use of
94 compression therapy unless the patient has arterial insufficiency, where it is
95 contraindicated.(20) Compression therapy promotes VLU healing by reducing the
96 hydrostatic pressure in lower limbs, enhancing venous return (20), and preventing venous
97 stasis (21). Research suggests that the use of below-knee multi-component compression
98 is efficacious and effective.(22-24) Consistent compression therapy is recommended to
99 prevent VLU recurrence.(22-24) Pharmaceutical, surgical, physiotherapy and other
100 methods can be used as adjunctive to compression, although the evidence of their
101 effectiveness is limited.(25) Other recommendations often include appropriate physical
102 activity, adequate nutrition, and leg elevation.(20) Of these, physical activity has received
103 mixed evidence on its efficacy when combined with compression (26, 27); however, it is
104 still generally recommended as the most recent evidence suggests that if patients adhere
105 to physical activity recommendations, venous insufficiency can improve, thus possibly
106 improve healing and reducing the risk of recurrence.(27, 28)

107 The best practice recommendations (exercise, compression) for treatment require
108 significant patient involvement; however, patient adherence to the VLU management
109 recommendations is often suboptimal.(26, 27) To optimise healing outcomes, VLU
110 patients should follow the management plan and understand the importance of
111 compression and other recommendations. The management plan should be developed in
112 collaboration with patients in a standard consultation (20, 29) because shared decision
113 making is paramount for a faster healing outcome.(30) An informed patient can
114 participate as an essential partner in the VLU management process.(33) The patient's role
115 is complementary to their health care professional's role, as they monitor symptoms,
116 adhere to compression, and adopt health behaviours, following the advice of health
117 professionals.(32, 34) However, the extent to which patients can follow the advice varies,
118 partially based on their HL.

119 Patient HL is defined as "the ability to obtain, process, and understand basic
120 health information and services needed to make appropriate health decisions and follow
121 instructions for treatment."(18, 19) There is a distinction between general health literacy
122 (often assessed through population-level surveys (31)), and specific HL which deals with
123 health skill and knowledge specific to the condition or disease.(32) General HL scales are
124 often used to assess a patient's general capabilities in navigating their health environment

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3 125 (e.g., where do you go for medical advice), often for the purpose of directing health
4 126 policy at a population scale. Meanwhile, specific HL scales assess individual capabilities
5 127 in dealing with a specific condition, like heart disease or diabetes. Both general and
6 128 VLU-specific HL may affect VLU outcomes through affecting patient's adoption of
7 129 health behaviours. Improvements in general and specific HL may improve patient
8 130 knowledge and understanding of the benefits of adhering to VLU self-management
9 131 recommendations (28-30) and support patients to adopt healthy behaviours in line with
10 132 the agreed plan. For example, when choosing compression hosiery, patients may rely on
11 133 HL to critique the options based on their analysis of comfort (33) which may be opposed
12 134 to achieving maximum therapeutic benefit.(34) Furthermore, HL may enhance their
13 135 compression application skills due to improved understanding of the manufacturer's
14 136 instructions.(24, 35) Finally, improved HL may influence patient understanding that
15 137 lifelong compression hosiery is recommended to prevent VLU recurrence.(26)
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19 139 **Study rationale**

20 140 Recent research has indicated that people vulnerable to VLUs, those with VLUs, and
21 141 those with other comorbidities tend to have concurrent deficits in HL.(36) VLU incidence
22 142 increases with age (13) and older people have been shown to have limited general HL.
23 143 (37) For example, although the 2015 European health literacy survey showed that
24 144 respondents received an average score of 33.8/50 (demonstrating "sufficient" health
25 145 literacy), the majority (58%+) of people aged over 66 years had limited health literacy,
26 146 compared to less than half of the general population.(31) A possible reason is internet
27 147 usage. Though internet use is proportional to increased HL (38), current research
28 148 consistently reports that older adults prefer to learn from their health care professionals,
29 149 (39) as opposed to independent learning through the use of the internet.(40) Qualitative
30 150 research has shown that VLU patients often discuss the volume of information and skills
31 151 that are needed for self-management upon VLU development as a significant burden, as
32 152 VLU self-management can be complex.(41) The education needs of VLU patients are not
33 153 well understood (42) resulting in unmet health literacy needs. In general, limited HL in
34 154 adults is associated with reduced adherence to treatment and health recommendations,
35 155 poorer health outcomes and increased cost of medical treatment (43), especially amongst
36 156 older adults.(44) Furthermore, checking on patient understanding is not a routine practice
37 157 for health care professionals (45), although this was recommended in at least one set of
38 158 international guidelines on VLU care.(29, 30)

39 159 Limited qualitative studies published in the past indicate that HL may affect VLU
40 160 patients' self-management capabilities (46-48), yet there have been no recent reviews
41 161 published examining the level of HL of patients with VLUs, and the effect it has on
42 162 patient's adoption of health behaviours. These studies suggest that inadequate HL reduces
43 163 the likelihood of engaging in VLU compression, but there is also the possibility that those
44 164 with lower HL may not increase their physical activity in response to a VLU (despite also
45 165 being in the recommendations). One educational intervention recent study (N=20)
46 166 indicated that specific HL in VLU is poor, but also demonstrated that there is utility in
47 167 improving HL in VLUs as patients, as they also felt more confident in their VLU
48 168 management afterwards.(49) However, this study did not examine physical activity rates,
49 169 and was hampered by a small sample size; therefore, most research in this field requires
50 170 further refinement.

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4 172 Furthermore, whether or not HL relates to VLU healing outcomes is not currently
5 173 known. In some studies, examining other illnesses including type 2 diabetes, HL has a
6 174 marginal effect on health outcomes. Therefore, the potentially mediating or moderating
7 175 effects of IT skills (50) and other psychological concepts, such as self-efficacy (51)
8 176 should be considered, as these factors have been suggested to play a role in HL's link to
9 177 healing outcomes.

10 178 Given that HL in VLU patients appears less extensively researched than other
11 179 factors in VLU healing, we opted to conduct a scoping review. The proposed scoping
12 180 review is a flexible method for identifying and discussing information useful for
13 181 answering our research questions, and allowing a holistic presentation of the available
14 182 literature on this topic.(52)

18 183 **Study objective**

19 184 The aim of this review is to scope the research examining the level of HL in VLU
20 185 patients, how this level may link to self-management behaviours (particularly exercise
21 186 and compression adherence), and their VLU healing generally. Findings of this scoping
22 187 review will guide the development of clinical practice guidelines on instructing VLU
23 188 patients according to their level of HL, as well as an assessment instrument for clinicians
24 189 caring for VLU patients. We anticipate that the findings of this review will aid
25 190 practitioners and public health officials in developing HL intervention programs. These
26 191 programs may improve VLU care and facilitate evidence-based practise through
27 192 improved knowledge translation.

30 193 **Protocol development**

31 194 We will conduct the review in accordance with the PRISMA Extended for Scoping
32 195 Reviews (PRISMA-ScR) outlined in Tricco et al. (24) (Table 1). Methods for this
33 196 scoping review were developed based on guidelines developed by Levac et al.(53) using
34 197 the six framework stages as outlined below.

37 198 **Stage 1: identifying the research question**

38 199 Based on the preliminary research we have developed the following research questions.

39 200 Our primary research question is:

40 201 1) What levels of HL (both general and specific) have been reported in adults with
41 202 active or past VLUs across outpatient, home care, community, and inpatient care?
42 203

43 204 Our secondary research questions are as follows:

44 205 2) Is there any relationship between HL and VLU patient adherence to compression
45 206 and/or exercise?

46 207 3) Is there any relationship between HL and VLU patient healing outcomes?
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212 Table 1. PRISMA(ScR) Checklist Adapted from PRISMA(ScR) (2018)

213

Section		Item	PRISMA-ScR Checklist	Check
Title		1	Identify the report as a scoping review.	
Abstract	Structured Summary	2	Provide a structured summary that includes (as applicable) background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	
Introduction	Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	
	Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	
Methods	Protocols and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	
	Eligibility Criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	
	Information Sources	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	
	Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
	Selection of evidence	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	
	Data charting process	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators	
	Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
	Critical appraisal of	12	If done, provide a rationale for conducting a critical appraisal of included sources	

	individual sources of evidence		of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate)	
	Summary measures	13	Not applicable for scoping reviews	
	Synthesis of results	14	Describe the methods of handling and summarizing the data that were charted	
	Risk of bias across studies	15	Not applicable for scoping reviews	
	Additional analyses	16	Not applicable for scoping reviews	
Results	Selection of sources of evidence	17	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram	
	Characteristics of sources of evidence	18	For each source of evidence, present characteristics for which data were charted and provide the citations.	
	Critical appraisal within sources of evidence	19	If done, present data on critical appraisal of included sources of evidence (see item 12)	
	Results of individual sources of evidence	20	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	
	Synthesis of results	21	Summarize and/or present the charting results as they relate to the review questions and objectives.	
	Risk of bias across studies	22	Not applicable for scoping reviews.	
	Additional analyses	23	Not applicable for scoping reviews	
Discussion	Summary of evidence	24	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	
	Limitations	25	Discuss the limitations of the scoping review process.	
	Conclusions	26	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	
Funding		27	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review	

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215 **Stage 2: identifying relevant studies**

216 This search strategy was developed by the research team with guidance from a medical
 217 librarian (CF). Eligible studies will be identified from eight databases: The Cochrane
 218 Database of Systematic Reviews; The Cochrane Wounds Specialised Register; The
 219 Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*);
 220 OvidMEDLINE; OvidMEDLINE (In-Process & Other Non-Indexed Citations); Ovid
 221 EMBASE; EBSCO CINAHL, Embase, and Google Scholar. We will also search trial
 222 registries, and reference lists of relevant publications for published and ongoing trials.
 223 The search will be limited to January 2000 to December 2020. The literature search will
 224 be developed using a combination of medical search headings and free text words.
 225 Keywords will be identified and selected from similar articles relevant to the population,
 226 concept, and context of the study. The keywords and search string relevant to Medline via
 227 Ovid can be found in supplementary Appendix 1. The full search will be conducted using
 228 Boolean operators and proximity operators, including wildcards, AND, OR, parentheses,
 229 quotations, and more as per the database used (Table 2).

231 Table 2. Ovid Medline search strategy. Identified search terms with truncated keywords
 232 and MeSH terms for the MEDLINE search via Ovid
 233

	Condition: active or past Venous Leg Ulcers.	Context: Reported levels of health literacy.	Concept: The effect of deficits in health literacy on patient's adherence to compression and effect on healing outcomes.
Text Words	Venous leg Ulcer* Venous ulcer* VLU Venous insufficiency Leg ulcer* Varicose ulcer*	Health Literacy Educat* Health promotion Health Information Health education Nurse-led education	Adher* Concord* Compl* Impact Effect Outcome
Medline	MeSH: Exp Leg Ulcer/	MeSH: Program Evaluation Exp Nursing Research Health education/ or consumer health information/ or health literacy/ or health promotion/ or healthy people programs/ or patient education as topic/ or teach-back communication/	MeSH: Attitude to health/ or health knowledge, attitudes, practice/ or "treatment adherence and compliance"/ or "patient acceptance of health care"/ or patient compliance/Recurrence treatment outcome/ or treatment failure/

	Health facilities/ or hospital units/ or hospitals/ or hospitals, community/ or hospitals, general/ or hospitals, high-volume/ or hospitals, low-volume/ or exp hospitals, private/ or exp hospitals, public/ or exp hospitals, rural/ or exp residential facilities/ or health services/ or exp community health services/ or health services for the aged/ or exp nursing care/ or exp nursing services/ or preventive health services/ or exp rural health services/	Wound Healing Secondary Prevention Self Care Stockings, Compression
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235 **Stage 3: study selection**

236 We will limit our search to papers published in English from January 2000 to December
 237 2020. Other languages will be excluded because the concept of health, and thus, the
 238 concept of health literacy, varies across languages (see (54, 55) for examples). Health
 239 literacy studies will be broadly defined to include studies that sought to assess specific
 240 (i.e., VLU-related) or general health knowledge (i.e., where to find general health
 241 information). This criterion is deliberately broad, as preliminary searches suggest there is
 242 scant literature on this topic. Our study selection will be guided by the following
 243 inclusion criteria:

- 244 Patients – patients with a current or previous VLU.
- 245 Settings – outpatient, community, home care, and inpatient care settings where
 246 VLU is managed.
- 247 Studies – peer reviewed reviews and studies (qualitative and quantitative)
 248 including randomized controlled trials, cohort, case control, quasi-experimental,
 249 cross-sectional, qualitative studies, literature reviews, scoping review guidelines,
 250 policies and protocols.
- 251 Studies that describe knowledge or education or general HL OR an intervention
 252 on this with measures at baseline/control group OR a domain relevant to VLU
 253 knowledge change will be included. Dependent variables include pre-post
 254 knowledge change OR pre-post change in general health literacy, OR description
 255 of health literacy at that state. For our secondary questions, dependent variables
 256 examined will be adherence to exercise recommendations OR adherence to
 257 compression in response to a VLU, or the healing rates of those with VLUs.

258 The following exclusion criteria will apply:

- 259 Patients – no diagnosis of VLU. Exclusion of diabetic foot ulcers, pressure ulcers,
 260 pressure injuries, vascular insufficiency.
- 261 Settings – no non-health care settings (e.g., mail out surveys at home)

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3 262 Studies – narrative reviews, opinions, commentary, conference proceedings.
4 263 Studies that did not examine knowledge, education or general HL and its
5 264 relationship with compression adherence will be excluded.
6
7 265 Selection of sources and evidence will take place in four stages.
8 266 Step A – initial retrieval, which will be performed by one researcher.
9 267 Step B – title screen. Titles that closely meet research aims will be retained. This step
10 268 will be performed by one researcher.
11 269 Step C – abstract screen. Abstracts will be retained if applicable to research aims.
12 270 This step will be performed by two researchers.
13 271 Step D – full text review. Articles retained if they comply with inclusion and
14 272 exclusion criteria. This will be performed by all authors of the research team. The
15 273 numbers of retrieved, assessed, excluded and retained articles will be documented
16 274 using a PRISMA flowchart (template in Figure 1).

19 275 **Stage 4: charting the data**

20 276 An Excel spreadsheet and/or Covidence will be utilised to chart the data. This database
21 277 will record the title and year of the publication, authors, study location, intervention type,
22 278 study population, aims of the study, overview of methods, outcome measures and results.
23 279 Duplicates will be removed via Endnote's duplicate detecting function.

26 280 **Stage 5: collating, summarising and reporting the results**

27 281 Full texts that are retained will undergo study quality assessment and critical appraisal in
28 282 order to determine the applicability of findings to clinical practice. We will use the CASP
29 283 (Critical Skills Appraisal Program)(56). Retained articles will be examined for any
30 284 qualitative or quantitative descriptions. Findings will be presented in a table that outlines
31 285 the study type, year the study was undertaken, sample size, study location, and patient
32 286 characteristics.

33 287 In order to assess the first research question, we will examine each study against
34 288 two types of HL: general HL (knowledge or skills) and VLU specific HL (knowledge or
35 289 skills). Findings and critical appraisal of the included articles will be provided in a
36 290 summary of findings and reported in CASP evidence profile table. This table will indicate
37 291 whether the paper suggested the majority of their sample lacked HL (general or specific).
38 292 We anticipate that there will be a highly heterogeneous definition of HL in these papers,
39 293 meaning that authors will be required to use their judgements as to whether or not the
40 294 paper is relevant, as a degree of simplification will be needed. All entries will be checked
41 295 by two authors. The lead author will resolve disagreements (if any) independently.

42 296 We aim to identify research gaps in the field of VLU treatments by displaying a
43 297 possible deficit in HL, which translates to lower abilities to adhere to self-management in
44 298 the form of compression and exercise. The findings are also expected to yield a number
45 299 of ways HL deficits in VLU patients can be addressed, thereby adding to care and
46 300 improving standards of care.

50 301 **Stage 6: Consultation—Patient and public involvement**

51 302 This scoping review is the first phase in a multistage research programme aimed at
52 303 developing a feasibility exercise program as an adjunct to compression intervention for
53 304 patients with VLUs. To ensure that our assessment of the existing evidence identifies and
54 305 includes the right target population we have the opportunity to include a consultation

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3 306 phase in this scoping review inviting people with VLUs and their families and caregivers
4 307 from an established Consumer Wounds Group to identify how HL impacts people with
5 308 VLUs to help identify whether the results of the scoping review reflect their needs.
6 309 We will map the evidence and identify research gaps and report on compression and
7 310 exercise treatments by investigating HL; which translates to lower abilities to adhere to
8 311 self-management in the form of compression and exercise.
9 312

313 **ETHICS AND DISSEMINATION**

314 All articles will be sourced from publicly available platforms. As such, this scoping
315 review will not require ethical approval. The findings from the scoping review will be
316 reported in a separate article and submitted to an open-access peer reviewed journal. The
317 results of this paper will provide an outline of the literature, which will be used to inform
318 future research into HL in patients with VLU. To facilitate knowledge translation and our
319 findings, we will liaise with Consumer Wounds Group. The published protocol and final
320 review will be promoted through social media platforms including Twitter and LinkedIn.
321 We will submit the final review at National and International Wound and Health
322 professional Conferences.
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324

325 **Figure legend**

326 Figure1. PRISMA Flowchart
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References

1. WHO. International classification of diseases for mortality and morbidity statistics. World Health Organisation.
2. Domingues EAR, Kaizer UAO, Lima MHM. Effectiveness of the strategies of an orientation programme for the lifestyle and wound - healing process in patients with venous ulcer: A randomised controlled trial. *Int Wound J* 2018;15(5):798-806.
3. Graves N, Zheng H. The prevalence and incidence of chronic wounds: a literature review. *Wound Pract Res* 2014;22(1):4-12.
4. Xie T, Ye J, Rerkasem K, Mani R. The venous ulcer continues to be a clinical challenge: an update. *Burns Trauma* 2018 Jun 15;6:18. doi: 10.1186/s41038-018-0119-y. eCollection 2018.
5. Meulendijks A, Franssen W, Schoonhoven L, Neumann H. A scoping review on chronic venous disease and the development of a venous leg ulcer: the role of obesity and mobility. *J Tissue Viability* 2020;29(3):190-196.
6. Weller CD, Team V, Ivory JD, Crawford K, Gethin G. ABPI reporting and compression recommendations in global clinical practice guidelines on venous leg ulcer management: A scoping review. *Int Wound J* 2019;16(2):406-19.
7. Pérez MB, López - Casanova P, Lavín RS, Torre HGdl, Verdú - Soriano J. Recent Reports from University of Alicante Highlight Findings in Leg Ulcers [Epidemiology of venous leg ulcers in primary health care: Incidence and prevalence in a health centre-A time series study (2010-2014)] Citation metadata. *Int Wound J* 2018;16(1).
8. Jockenhöfer F, Gollnick H, Herberger K, Isbary G, Renner R, Stücker M, et al. Aetiology, comorbidities and cofactors of chronic leg ulcers: retrospective evaluation of 1 000 patients from 10 specialised dermatological wound care centers in Germany. *Int Wound J* 2016;13(5):821-8.
9. Thistlethwaite KR, Finlayson KJ, Cooper PD, Brown B, Bennett MH, Kay G, et al. The effectiveness of hyperbaric oxygen therapy for healing chronic venous leg ulcers: A randomized, double - blind, placebo - controlled trial. *Wound Repair Regen* 2018;26(4):324-31.
10. Finlayson KJ, Parker CN, Miller C, Gibb M, Kapp S, Ogrin R, et al. Predicting the likelihood of venous leg ulcer recurrence: The diagnostic accuracy of a newly developed risk assessment tool. *Int Wound J*. 2018;15(5):686-94.
11. Santler B, Goerge T. Chronic venous insufficiency—a review of pathophysiology, diagnosis, and treatment. *J Dtsch Dermatol Ges* 2017;15(5):538-56.
12. Weller C, Ademi Z, Makarounas-Kirchmann K, Stoelwinder J. Economic evaluation of compression therapy in venous leg ulcer randomised controlled trials: A systematic review. *Wound Pract Res* 2012;20(1):1-12.
13. Cheng Q, Gibb M, Graves N, Pacella R. Cost-effectiveness analysis of guideline-based optimal care for venous leg ulcers in Australia. *BMC Health Serv Res* 2018;18(421):1-14.
14. Nussbaum SR, Carter MJ, Fife CE, DaVanzo J, Haught R, Nusgart M, et al. An economic evaluation of the impact, cost, and medicare policy implications of chronic nonhealing wounds. *Value Health* 2018;21(1):27-32.

- 1
2
3 374 15. Tricco AC, Lillie E, Zarin W, O'Brien K, Colquhoun H, Kastner M, et al. A
4 375 scoping review on the conduct and reporting of scoping reviews. *BMC Med Res*
5 376 *Methodol* 2016 Feb 9;16:15. doi: 10.1186/s12874-016-0116-4.
- 6 377 16. Ruseckaite R, Richards C, Rutherford C, Team V, Turnour L, Franks P, et al. A
7 378 conceptual framework of patient-reported outcomes in people with venous leg ulcers.
8 379 *Wound Repair Regen* 2020;28(3):355-363.
- 9 380 17. Cheng Q, Kularatna S, Lee XJ, Graves N, Pacella RE. Comparison of EQ-5D-5L
10 381 and SPVU-5D for measuring quality of life in patients with venous leg ulcers in an
11 382 Australian setting. *Qual Life Res* 2019;28(7):1903-11.
- 12 383 18. Barnsbee L, Cheng Q, Tulleners R, Lee X, Brain D, Pacella R. Measuring costs
13 384 and quality of life for venous leg ulcers. *Int Wound J* 2019;16(1):112-21.
- 14 385 19. Pacella R, Tulleners R, Cheng Q, Burkett E, Edwards H, S Y, et al. Solutions to
15 386 the chronic wounds problem in Australia: a call to action. *Wound Pract Res*
16 387 2018;26(2):84-98.
- 17 388 20. Australian Wound Management Association Inc., New Zealand Wound Care
18 389 Society Inc. Australian and New Zealand Practice Guideline for Prevention and
19 390 Management of Venous Leg Ulcers. October 2011; 2011.
- 20 391 21. Team V, Chandler PG, Weller CD. Adjuvant therapies in venous leg ulcer
21 392 management: A scoping review. *Wound Repair Regen*. 2019;27(5):562-90.
- 22 393 22. Australian Wound Management Association. KPMG Health Econ report: An
23 394 economic evaluation of compression therapy for venous leg ulcers. Canberra: Australian
24 395 Wound Management Association; 2013.
- 25 396 23. Andriessen A, Apelqvist J, Mosti G, Partsch H, Gonska C, Abel M. Compression
26 397 therapy for venous leg ulcers: risk factors for adverse events and complications,
27 398 contraindications - a review of present guidelines. *J Eur Acad Dermatol Venereol*.
28 399 2017;31(9):1562-8.
- 29 400 24. O'Meara S, Cullum N, Nelson E, Dumville J. Compression for venous leg ulcers.
30 401 *Cochrane Database Syst Rev*. 2012 Nov 14;11(11):CD000265.
- 31 402 25. Team V, Chandler PG, Weller CD. Adjuvant therapies in venous leg ulcer
32 403 management: a scoping review. *Wound Repair Regen*. 2019;27(5):562-90.
- 33 404 26. Klionizakis M, Tew G, Gumber A, Crank H, King B, Middleton G, et al.
34 405 Supervised exercise training as an adjunct therapy for venous leg ulcers: a randomized
35 406 controlled feasibility trial. *Br J Dermatol* 2018;178(5):1072-82.
- 36 407 27. Jull A, Slark J, Parsons J. Prescribed Exercise With Compression vs Compression
37 408 Alone in Treating Patients With Venous Leg Ulcers: A Systematic Review and Meta-
38 409 analysis. *JAMA Dermatol*. 2018;154(11):1304-11.
- 39 410 28. Orr L, Klement KA, McCrossin L, O'Sullivan Drombolis D, Houghton PE,
40 411 Spaulding S, et al. A Systematic Review and Meta-analysis of Exercise Intervention for
41 412 the Treatment of Calf Muscle Pump Impairment in Individuals with Chronic Venous
42 413 Insufficiency. *Ostomy Wound Manage*. 2017;63(8):30-43.
- 43 414 29. Franks PJ, Barker J, Collier M, Gethin G, Haesler E, Jawien A, et al. Management
44 415 of patients with venous leg ulcers: challenges and current best practice. *J Wound Care*
45 416 2016;25(Sup6):S1-S67.
- 46 417 30. Gethin G, Probst S, Stryja J, Christiansen N, Price P. Evidence in Person-Centred
47 418 Care in Chronic Wound Care: A systematic Review and Recommendations for Practice. *J*
48 419 *Wound Care*. In Press.

- 1
2
3 420 31. Sørensen K, Pelikan JM, Röthlin F, Ganahl K, Slonska Z, Doyle G, et al. Health
4 421 literacy in Europe: comparative results of the European health literacy survey (HLS-EU).
5 422 Eur J Public Health 2015;25(6):1053-8.
- 6 423 32. Yamashita T, Kart CS. Is diabetes - specific health literacy associated with
7 424 diabetes - related outcomes in older adults? J Diabetes 2011;3(2):138-46.
- 8 425 33. Boxall SL, Carville K, Leslie GD, Jansen S. Compression bandaging:
9 426 Identification of factors contributing to non-concordance. Wound Pract Res
10 427 2019;27(1):6-20.
- 11 428 34. Muldoon J. Compression hosiery for venous conditions: a literature review. J
12 429 Community Nurs 2019;33(4):29-34.
- 13 430 35. Shi C, Dumville JC, Cullum N. Compression bandages or stockings versus no
14 431 compression for treating venous leg ulcers. Cochrane Database Syst Rev 2019 Aug
15 432 12;2019(8):CD013397. doi: 10.1002/14651858.CD013397. PMID: PMC6690563.
- 16 433 36. Australian Institute of Health and Welfare. Australia's health 2018. Australia's
17 434 health series no. 16. AUS 221. Canberra: AIHW; 2018.
- 18 435 37. Baker DW, Wolf MS, Feinglass J, Thompson JA. Health literacy, cognitive
19 436 abilities, and mortality among elderly persons. J Gen Intern Med 2008;23(6):723-6.
- 20 437 38. Yamashita T, Bardo AR, Liu D, Cummins PA. Literacy, numeracy, and health
21 438 information seeking among middle-aged and older adults in the United States. J Aging
22 439 Health 2020;32(1):33-41.
- 23 440 39. Turner AM, Osterhage KP, Taylor JO, Hartzler AL, Demiris G, editors. A closer
24 441 look at health information seeking by older adults and involved family and friends:
25 442 design considerations for health information technologies. AMIA Annual Symposium
26 443 Proceedings; 2018: American Medical Informatics Association.
- 27 444 40. Chaudhuri S, Le T, White C, Thompson J, Demiris G. Examining health
28 445 information-seeking behaviors of older adults. Comput Inform Nurs 2013
29 446 Nov;31(11):547-53. doi: 10.1097/01.NCN.0000432131.92020.42. PMID: 23974574;
30 447 PMID: PMC4062544.
- 31 448 41. Chase SK, Melloni M, Savage A. A forever healing: the lived experience of
32 449 venous ulcer disease. J Vasc Nurs 1997;15(2):73-8.
- 33 450 42. Shanley E, Moore Z, Patton D, O'Connor T, Nugent L, Budri AM, et al. Patient
34 451 education for preventing recurrence of venous leg ulcers: a systematic review. J Wound
35 452 Care 2020;29(2):79-91.
- 36 453 43. Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health
37 454 literacy and health outcomes: an updated systematic review. Ann Intern Med
38 455 2011;155(2):97-107.
- 39 456 44. MacLeod S, Musich S, Gulyas S, Cheng Y, Tkatch R, Cempellin D, et al. The
40 457 impact of inadequate health literacy on patient satisfaction, healthcare utilization, and
41 458 expenditures among older adults. Geriatr Nurs 2017;38(4):334-41.
- 42 459 45. Graham S, Brookey J. Do patients understand? Perm J 2008;12(3):67.
- 43 460 46. Walshe C. Living with a venous leg ulcer: a descriptive study of patients'
44 461 experiences. J Adv Nurs 1995;22(6):1092-100.
- 45 462 47. Chase SK, Whittemore R, Crosby N, Freney D, Howes P, Phillips TJ. Living with
46 463 chronic venous leg ulcers: a descriptive study of knowledge and functional health status.
47 464 J Community Health Nurs. 2000;17(1):1-13.

- 1
2
3 465 48. Probst S, Sechaud L, Bobbink P, Skinner MB, Weller CD. The lived experience
4 466 of recurrence prevention in patients with venous leg ulcers: An interpretative
5 467 phenomenological study. *J Tissue Viability*. 2020;29(3):176-9.
6 468 49. Clarke C, Whitmore L, Webb A. Patient education pictorial boards: improving
7 469 patients' understanding of venous leg ulcer and compression therapy. *Wounds UK*.
8 470 2020;16(2).
9 471 50. Boren SA. A review of health literacy and diabetes: opportunities for technology.
10 472 *J Diabetes Sci Technol*. 2009;3(1):202-9.
11 473 51. Xu XY, Leung AYM, Chau PH. Health literacy, self-efficacy, and associated
12 474 factors among patients with diabetes. *Health Lit Res Pract* 2018;2(2):e67-e77.
13 475 52. Pham MT, Rajić A, Greig JD, Sargeant JM, Papadopoulos A, McEwen SA. A
14 476 scoping review of scoping reviews: advancing the approach and enhancing the
15 477 consistency. *Res Synth Methods* 2014;5(4):371-85.
16 478 53. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al.
17 479 PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Ann*
18 480 *Intern Med* 2018;169(7):467-73.
19 481 54. Choi TS, Walker KZ, Ralston RA, Palermo C. Diabetes education needs of
20 482 Chinese Australians: A qualitative study. *Health Educ J* 2015;74(2):197-208.
21 483 55. Walker C, Weeks A, McAvoy B, Demetriou E. Exploring the role of self -
22 484 management programmes in caring for people from culturally and linguistically diverse
23 485 backgrounds in Melbourne, Australia. *Health Expect* 2005;8(4):315-23.
24 486 56. Singh J. Critical appraisal skills programme. *J Pharmacol Pharmacother*
25 487 2013;4(1):76-77.
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510 Authorship

511 CW provided substantial contributions to the conception and design of the work, revisited
512 it critically for important intellectual content, provided final approval of the submitted
513 version and an agreement to be accountable for all aspects of the work in ensuring that
514 questions related to the accuracy or integrity of any part of the work are appropriately
515 investigated and resolved.

516
517 VT provided substantial contributions to the conception and design of the work, produced
518 the first draft, revisited it critically for important intellectual content, provided final
519 approval of the submitted version and an agreement to be accountable for all aspects of
520 the work in ensuring that questions related to the accuracy or integrity of any part of the
521 work are appropriately investigated and resolved.

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523 SP provided substantial contributions to the conception and design of the work, revisited
524 it critically for important intellectual content, provided final approval of the submitted
525 version and an agreement to be accountable for all aspects of the work in ensuring that
526 questions related to the accuracy or integrity of any part of the work are appropriately
527 investigated and resolved.

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529 GG provided substantial contributions to the conception and design of the work, revisited
530 it critically for important intellectual content, provided final approval of the submitted
531 version and an agreement to be accountable for all aspects of the work in ensuring that
532 questions related to the accuracy or integrity of any part of the work are appropriately
533 investigated and resolved.

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535 CR provided substantial contributions to the conception and design of the work, produced
536 the first draft, with the support of a librarian has developed a search strategy, provided
537 final approval of the submitted version and an agreement to be accountable for all aspects
538 of the work in ensuring that questions related to the accuracy or integrity of any part of
539 the work are appropriately investigated and resolved.

540
541 JS provided substantial contributions to the conception and design of the work, revisited
542 it critically for important intellectual content, provided final approval of the submitted
543 version and an agreement to be accountable for all aspects of the work in ensuring that
544 questions related to the accuracy or integrity of any part of the work are appropriately
545 investigated and resolved.

546
547 LT provided substantial contributions to the conception and design of the work, revisited
548 it critically for important intellectual content, provided final approval of the submitted
549 version and an agreement to be accountable for all aspects of the work in ensuring that
550 questions related to the accuracy or integrity of any part of the work are appropriately
551 investigated and resolved.

552
553 AB provided substantial contributions to the conception and design of the work,
554 produced the first draft, revisited it critically for important intellectual content, provided
555 final approval of the submitted version and an agreement to be accountable for all aspects

1
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3 556 of the work in ensuring that questions related to the accuracy or integrity of any part of
4 557 the work are appropriately investigated and resolved.
5 558

7 559 **Guarantor of the review**

8 560
9 561 Professor Carolina Weller
10 562

12
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20 569 Medical Research Council (APP1069329). Other co-authors received no specific grant
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23
24 571 **Conflicts of interest**

25 572 We have read and understood BMJ policy on declaration of interests and declare that we
26 573 have no competing interests.

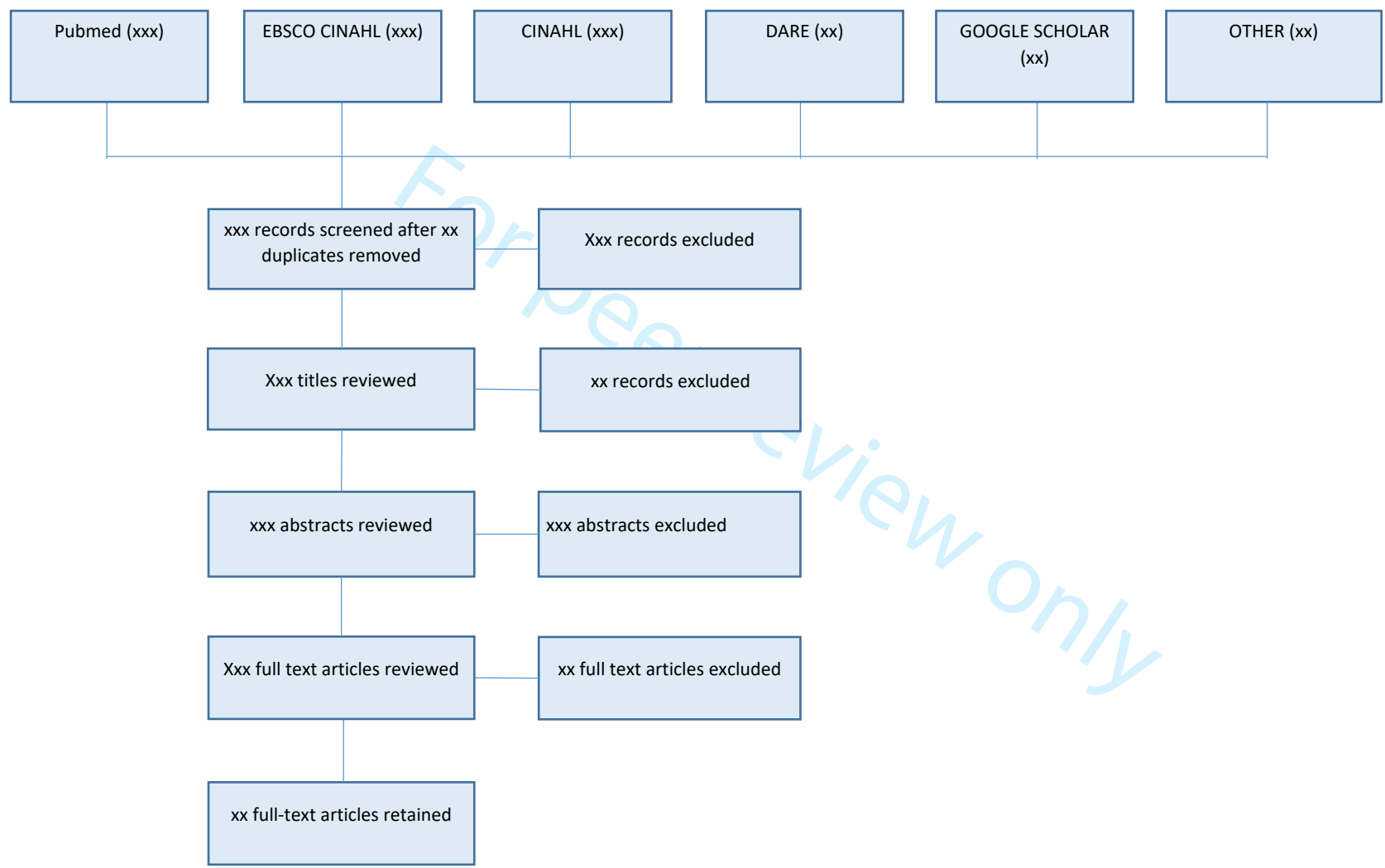
27 574
28 575 **Data statement**

29 576 Not applicable.

31 577 **Abbreviations**

32 578 HL: Health Literacy
33 579 VLU: Venous Leg Ulcer
34 580 CVI: Chronic Venous Insufficiency
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Figure 1. PRISMA flowchart



Appendix 1: Search strings for MEDLINE via Ovid

- 1 exp Leg Ulcer/
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 8 2 (venous leg ulcer* or Venous ulcer* or VLU or Venous insufficiency or Leg ulcer* or Varicose
 9 ulcer*).mp. [mp=title, abstract, original title, name of substance word, subject heading word,
 10 floating sub-heading word, keyword heading word, organism supplementary concept word, protocol
 11 supplementary concept word, rare disease supplementary concept word, unique identifier,
 12 synonyms]
 13
 14 3 1 or 2
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 16 4 Program Evaluation/
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 18 5 exp Nursing Research/
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 20 6 health education/ or consumer health information/ or health literacy/ or health promotion/ or healthy
 21 people programs/ or patient education as topic/ or teach-back communication/
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 23 7 health facilities/ or hospital units/ or hospitals/ or hospitals, community/ or hospitals, general/ or
 24 hospitals, high-volume/ or hospitals, low-volume/ or exp hospitals, private/ or exp hospitals, public/
 25 or exp hospitals, rural/ or exp residential facilities/ or health services/ or exp community health
 26 services/ or health services for the aged/ or exp nursing care/ or exp nursing services/ or preventive
 27 health services/ or exp rural health services/
 28
 29 8 (Know* adj2 (health or disease or Illness)).mp. [mp=title, abstract, original title, name of substance
 30 word, subject heading word, floating sub-heading word, keyword heading word, organism
 31 supplementary concept word, protocol supplementary concept word, rare disease supplementary
 32 concept word, unique identifier, synonyms]
 33
 34 9 (Health adj2 (educat* or literacy or interest or understanding)).mp. [mp=title, abstract, original title,
 35 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
 36 organism supplementary concept word, protocol supplementary concept word, rare disease
 37 supplementary concept word, unique identifier, synonyms]
 38
 39 10 (Interest* adj2 health interest).mp. [mp=title, abstract, original title, name of substance word, subject
 40 heading word, floating sub-heading word, keyword heading word, organism supplementary concept
 41 word, protocol supplementary concept word, rare disease supplementary concept word, unique
 42 identifier, synonyms]
 43
 44 11 (Information adj2 (dissemination or access or services or technology)).mp. [mp=title, abstract,
 45 original title, name of substance word, subject heading word, floating sub-heading word, keyword
 46 heading word, organism supplementary concept word, protocol supplementary concept word, rare
 47 disease supplementary concept word, unique identifier, synonyms]
 48
 49 12 (Teach* adj materials).mp. [mp=title, abstract, original title, name of substance word, subject
 50 heading word, floating sub-heading word, keyword heading word, organism supplementary concept
 51 word, protocol supplementary concept word, rare disease supplementary concept word, unique
 52 identifier, synonyms]
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 54 13 (Health Literacy or Educat* or Health promotion or Nurse-led education).mp. [mp=title, abstract,
 55 original title, name of substance word, subject heading word, floating sub-heading word, keyword
 56 heading word, organism supplementary concept word, protocol supplementary concept word, rare
 57 disease supplementary concept word, unique identifier, synonyms]
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- 14 Recurrence/
- 15 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
- 16 attitude to health/ or health knowledge, attitudes, practice/ or "treatment adherence and compliance"/ or "patient acceptance of health care"/ or patient compliance/ or treatment refusal/
- 17 Recurrence/
- 18 treatment outcome/ or treatment failure/
- 19 Wound Healing/
- 20 Secondary Prevention/
- 21 Self Care/
- 22 Stockings, Compression/
- 23 (Adher* adj2 (compression or self care or self management)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 24 (Concord* adj2 (compression or self care or self management)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 25 (Compl* adj2 (compression or self care or self management)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 26 (Adher* or Concord* or Compl* or Impact or Effect or Outcome or Adher* or Healing or Recur* or Compress* or self care or Self manag* or health behavior*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]
- 27 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
- 28 3 and 15 and 27

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preorting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	N/A
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1

1	Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	16-17
2				
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4	Amendments			
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7		#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
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14	Support			
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16	Sources	#5a	Indicate sources of financial or other support for the review	17
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18	Sponsor	#5b	Provide name for the review funder and / or sponsor	17
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21	Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
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25	Introduction			
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27	Rationale	#6	Describe the rationale for the review in the context of what is already known	4
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31	Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
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36	Methods			
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38	Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5-6
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45	Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	8
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52	Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Table 2 8-9
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1	Study records -	#11a	Describe the mechanism(s) that will be used to manage	9-10
2	data management		records and data throughout the review	
3				
4	Study records -	#11b	State the process that will be used for selecting studies	9
5	selection process		(such as two independent reviewers) through each phase	
6			of the review (that is, screening, eligibility and inclusion in	
7			meta-analysis)	
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11	Study records -	#11c	Describe planned method of extracting data from reports	10
12	data collection		(such as piloting forms, done independently, in duplicate),	
13	process		any processes for obtaining and confirming data from	
14			investigators	
15				
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18	Data items	#12	List and define all variables for which data will be sought	9
19			(such as PICO items, funding sources), any pre-planned	
20			data assumptions and simplifications	
21				
22				
23				
24	Outcomes and	#13	List and define all outcomes for which data will be sought,	10
25	prioritization		including prioritization of main and additional outcomes,	
26			with rationale	
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29	Risk of bias in	#14	Describe anticipated methods for assessing risk of bias of	10
30	individual studies		individual studies, including whether this will be done at the	
31			outcome or study level, or both; state how this information	
32			will be used in data synthesis	
33				
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36	Data synthesis	#15a	Describe criteria under which study data will be	10
37			quantitatively synthesised	
38				
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40	Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe	N/A
41			planned summary measures, methods of handling data and	
42			methods of combining data from studies, including any	
43			planned exploration of consistency (such as I ² , Kendall's τ)	
44				
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46	Data synthesis	#15c	Describe any proposed additional analyses (such as	N/A
47			sensitivity or subgroup analyses, meta-regression)	
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50	Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the	N/A
51			type of summary planned	
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54	Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as	N/A
55			publication bias across studies, selective reporting within	
56			studies)	
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1 Confidence in #17 Describe how the strength of the body of evidence will be 10
2 cumulative assessed (such as GRADE)
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7 CC-BY 4.0. This checklist was completed on 07. September 2020 using
8 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with
9 [Penelope.ai](#)
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Health literacy in people with venous leg ulcers: A protocol for scoping review

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**Health literacy in people with Venous Leg Ulcers:
A protocol for scoping review**

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Health literacy in people with Venous Leg Ulcers: A protocol for scoping review

Abstract

Introduction: Chronic venous leg ulcer (VLU) healing is a complex clinical problem. It requires intervention from skilled, costly, multidisciplinary wound-care teams, working with patients to manage their care. Compression therapy has been shown to help heal venous ulcers and to reduce recurrence, with some evidence suggesting the value of exercise as well. These activities require health education and health literacy (HL) as patients must process, understand and consistently apply health information for successful self-management. Research suggests that those most vulnerable to VLUs also tend to have limited HL, but there have been no reviews examining the state of HL in patients with previous or active VLUs. This scoping review (ScR) aims to examine the level of HL in VLU patients and how HL may link to self-management behaviours (particularly exercise and compression adherence), and their VLU healing generally.

Methods and analysis: We will use Preferred Reporting Items for Systematic Reviews and Meta-Analyses Scoping Review guidelines and the Levac methodology framework to explore eligible papers that examine the effect of HL on their exercise and compression adherence. Electronic databases will be searched (MEDLINE, EMBASE, the Cochrane Library, PsycInfo and Health, OpenGray), examining for all papers on these subjects published between 2000 and 2020. All studies describing compression and or exercise during VLU management will be included. Study characteristics will be recorded; qualitative data will be extracted and evaluated. Quantitative data will be extracted and summarized.

Ethics and dissemination: We will disseminate results through peer-reviewed publications. We will use data (i.e., journal articles) from publicly available platforms; so, this study does not require ethical review. The consultation step will be carried out with patients, carers and health professionals as part of an established wound consumer group.

Keywords: Venous Leg Ulcers; Health Literacy; Health Education; Compression; Compression Adherence

Article summary

Strengths and limitations of this study

- This scoping review protocol is the first to focus on the role of consumers' health literacy in venous leg ulcer management.
- In order to ensure a systematic approach to searching, screening and reporting, we utilise the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews tool, the most current guidance on conducting scoping reviews.
- We have included a comprehensive search strategy and data extraction template.
- The studies included in the review will be appraised for quality.

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3 80 • Studies published outside of the indicated databases may be missed.
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For peer review only

81 INTRODUCTION

82 Venous leg ulcers (VLUs) are chronic skin ulcers mainly affecting the gaiter area, most
83 often caused by continuous venous hypertension or chronic venous insufficiency.(1)
84 VLUs are a common health condition, affecting approximately 1-3% of people globally.
85 (2-4) This is often due to persistent high blood pressure in varicose veins.(5, 6) The
86 prevalence of VLU increases with age, doubling among those aged over 65 years.(7)
87 People with VLU often have various other comorbidities, including arterial hypertension,
88 obesity, non-insulin dependent diabetes and dyslipidaemia.(8) VLU healing, defined as
89 complete wound re-epithelization,(9) is often slow. The chance of recurrence of a healed
90 VLU is high.(10, 11) The cycle of healing and frequent recurrent episodes has significant
91 economic impact (4, 12-15) and severely affects VLU patients' health and wellbeing,
92 including that of their families.(16-18) Despite advances in treatments, sustained healing
93 of VLU continues to be an ongoing problem for patients, health services, and health
94 systems.(19)

95 Current best practice recommendation for people with active VLU is the use of
96 compression therapy unless the patient has arterial insufficiency, where it is
97 contraindicated.(20) Compression therapy promotes VLU healing by reducing the
98 hydrostatic pressure in lower limbs, enhancing venous return (20), and preventing venous
99 stasis (21). Research suggests that the use of below-knee multi-component compression
100 is efficacious and effective.(22-24) Consistent compression therapy is recommended to
101 prevent VLU recurrence.(22-24) Pharmaceutical, surgical, physiotherapy and other
102 methods can be used as adjunctive to compression, although the evidence of their
103 effectiveness is limited.(25) Other recommendations often include appropriate physical
104 activity, adequate nutrition, and leg elevation.(20) Of these, physical activity has received
105 mixed evidence on its efficacy when combined with compression.(26, 27) However, it is
106 still generally recommended as the most recent evidence suggests that if patients adhere
107 to physical activity recommendations, venous insufficiency can improve, thus possibly
108 improve healing and reducing the risk of recurrence.(27, 28)

109 The best practice recommendations (exercise, compression) for treatment require
110 significant patient involvement; however, patient adherence to the VLU management
111 recommendations is often suboptimal.(26, 27) To optimise healing outcomes, VLU
112 patients should follow the management plan and understand the importance of
113 compression and other recommendations. The management plan should be developed in
114 collaboration with patients in a standard consultation (20, 29) because shared decision
115 making is paramount for a faster healing outcome.(30) An informed patient can
116 participate as an essential partner in the VLU management process.(31)The patient's role
117 is complementary to their health care professional's role, as they monitor symptoms,
118 adhere to compression, and adopt health behaviours, following the advice of health
119 professionals.(32, 33) However, the extent to which patients can follow the advice varies,
120 partially based on their HL.

121 Patient HL is defined as "the ability to obtain, process, and understand basic
122 health information and services needed to make appropriate health decisions and follow
123 instructions for treatment."(18, 19) There is a distinction between general health literacy
124 often assessed through population-level surveys (34), and specific HL which deals with
125 health skill and knowledge specific to the condition or disease.(32) General HL scales are
126 often used to assess a patient's general capabilities in navigating their health environment

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3 127 (e.g., where do you go for medical advice), often for the purpose of directing health
4 128 policy at a population scale. Meanwhile, specific HL scales assess individual capabilities
5 129 in dealing with a specific condition, like heart disease or diabetes. Both general and
6 130 VLU-specific HL may affect VLU outcomes through affecting patient's adoption of
7 131 health behaviours. Improvements in general and specific HL may improve patient
8 132 knowledge and understanding of the benefits of adhering to VLU self-management
9 133 recommendations (28-30) and support patients to adopt healthy behaviours in line with
10 134 the agreed plan. For example, when choosing compression hosiery, patients may rely on
11 135 HL to critique the options based on their analysis of comfort (31) which may be opposed
12 136 to achieving maximum therapeutic benefit.(33) Furthermore, HL may enhance their
13 137 compression application skills due to improved understanding of the manufacturer's
14 138 instructions.(24, 35) Finally, improved HL may influence patient understanding that
15 139 lifelong compression hosiery is recommended to prevent VLU recurrence.(26)
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19 141 **Study rationale**

20 142 Recent research has indicated that people vulnerable to VLUs, those with VLUs, and
21 143 those with other comorbidities tend to have concurrent deficits in HL.(36) VLU incidence
22 144 increases with age (13) and older people have been shown to have limited general HL.
23 145 (37) For example, although the 2015 European health literacy survey showed that
24 146 respondents received an average score of 33.8/50 (demonstrating "sufficient" health
25 147 literacy), the majority (58%) of people aged over 66 years had limited health literacy,
26 148 compared to less than half of the general population.(34) A possible reason is internet
27 149 usage. Though internet use is proportional to increased HL (38), current research
28 150 consistently reports that older adults prefer to learn from their health care professionals,
29 151 (39) as opposed to independent learning through the use of the internet.(40) Qualitative
30 152 research has shown that VLU patients often discuss the volume of information and skills
31 153 that are needed for self-management upon VLU development as a significant burden, as
32 154 VLU self-management can be complex.(41) The education needs of VLU patients are not
33 155 well understood (42) resulting in unmet health literacy needs. In general, limited HL in
34 156 adults is associated with reduced adherence to treatment and health recommendations,
35 157 poorer health outcomes and increased cost of medical treatment (43), especially amongst
36 158 older adults.(44) Furthermore, checking on patient understanding is not a routine practice
37 159 for health care professionals (45), although this was recommended in at least one set of
38 160 international guidelines on VLU care.(29, 30)

39 161 Limited qualitative studies published in the past indicate that HL may affect VLU
40 162 patients' self-management capabilities (46-48), yet there have been no recent reviews
41 163 published examining the level of HL of patients with VLUs, and the effect it has on
42 164 patient's adoption of health behaviours. These studies suggest that inadequate HL reduces
43 165 the likelihood of engaging in VLU compression, but there is also the possibility that those
44 166 with lower HL may not increase their physical activity in response to a VLU (despite also
45 167 being in the recommendations). One educational intervention study (N=20) indicated that
46 168 specific HL in VLU is poor, but also demonstrated that there is utility in improving HL in
47 169 VLU patients. The authors reported that patients felt more confident in VLU management
48 170 after the educational intervention.(49) However, this study did not examine physical
49 171 activity rates, and was hampered by a small sample size. Therefore, most research in this
50 172 field requires further refinement.

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4 174 Furthermore, whether or not HL relates to VLU healing outcomes is not currently
5 175 known. In some studies, examining other illnesses including type 2 diabetes, HL has a
6 176 marginal effect on health outcomes. For example, two studies on diabetic foot ulcers have
7 177 found that lower levels of HL were linked to inappropriate self-care and delayed wound
8 178 healing (50, 51). Furthermore, the potentially mediating or moderating effects of IT skills
9 179 (52) and other psychological concepts, such as self-efficacy (53) should be considered, as
10 180 these factors have been suggested to play a role in HL's link to healing outcomes.

11 181
12 182 Given that HL in VLU patients appears less extensively researched than other
13 183 factors in VLU healing, we opted to conduct a scoping review. The proposed scoping
14 184 review is a flexible method for identifying and discussing information useful for
15 185 answering our research questions, and allowing a holistic presentation of the available
16 186 literature on this topic.(54)

19 186 **Study objective**

20 187 The aim of this review is to scope the research examining the level of HL in VLU
21 188 patients, and how this level may link to self-management behaviours (particularly
22 189 exercise and compression adherence), and their VLU healing generally. Findings of this
23 190 scoping review will guide the development of clinical practice guidelines on instructing
24 191 VLU patients according to their level of HL, as well as an assessment instrument for
25 192 clinicians caring for VLU patients. We anticipate that the findings of this review will aid
26 193 practitioners and public health officials in developing HL intervention programs. These
27 194 programs may improve VLU care and facilitate evidence-based practise through
28 195 improved knowledge translation.

31 196 **Protocol development**

32 197 We will conduct the review in accordance with the PRISMA Extended for Scoping
33 198 Reviews (PRISMA-ScR) outlined in Tricco et al. (24) (Table 1). Methods for this
34 199 scoping review were developed based on guidelines developed by Levac et al.(55) using
35 200 the six framework stages as outlined below.

38 201 **Stage 1: identifying the research question**

39 202 Based on the preliminary research we have developed the following research questions.

40 203 Our primary research question is:

41 204 1) What levels of HL (both general and specific) have been reported in adults with
42 205 active or past VLUs across outpatient, home care, community, and inpatient care?
43 206

44 207 Our secondary research questions are as follows:

45 208 2) Is there any relationship between HL and VLU patient adherence to compression
46 209 and/or exercise?
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48 210 3) Is there any relationship between HL and VLU patient healing outcomes?
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215 Table 1. PRISMA(ScR) Checklist Adapted from PRISMA(ScR) (2018)

216

Section		Item	PRISMA-ScR Checklist	Check
Title		1	Identify the report as a scoping review.	
Abstract	Structured Summary	2	Provide a structured summary that includes (as applicable) background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	
Introduction	Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	
	Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	
Methods	Protocols and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	
	Eligibility Criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	
	Information Sources	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	
	Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
	Selection of evidence	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	
	Data charting process	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators	
	Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
	Critical appraisal of	12	If done, provide a rationale for conducting a critical appraisal of included sources	

	individual sources of evidence		of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate)	
	Summary measures	13	Not applicable for scoping reviews	
	Synthesis of results	14	Describe the methods of handling and summarizing the data that were charted	
	Risk of bias across studies	15	Not applicable for scoping reviews	
	Additional analyses	16	Not applicable for scoping reviews	
Results	Selection of sources of evidence	17	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram	
	Characteristics of sources of evidence	18	For each source of evidence, present characteristics for which data were charted and provide the citations.	
	Critical appraisal within sources of evidence	19	If done, present data on critical appraisal of included sources of evidence (see item 12)	
	Results of individual sources of evidence	20	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	
	Synthesis of results	21	Summarize and/or present the charting results as they relate to the review questions and objectives.	
	Risk of bias across studies	22	Not applicable for scoping reviews.	
	Additional analyses	23	Not applicable for scoping reviews	
Discussion	Summary of evidence	24	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	
	Limitations	25	Discuss the limitations of the scoping review process.	
	Conclusions	26	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	
Funding		27	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review	

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218 Stage 2: identifying relevant studies

219 This search strategy was developed by the research team with guidance from a medical
 220 librarian (CF). Eligible studies will be identified from eight databases: The Cochrane
 221 Database of Systematic Reviews; The Cochrane Wounds Specialised Register; The
 222 Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*);
 223 OvidMEDLINE; OvidMEDLINE (In-Process & Other Non-Indexed Citations); Ovid
 224 EMBASE; EBSCO CINAHL, Embase, and Google Scholar. We will also search trial
 225 registries, and reference lists of relevant publications for published and ongoing trials.
 226 The search will be limited to January 2000 to December 2020. The literature search will
 227 be developed using a combination of medical search headings and free text words.
 228 Keywords will be identified and selected from similar articles relevant to the population,
 229 concept, and context of the study. The keywords and search string relevant to Medline via
 230 Ovid can be found in supplementary Appendix 1. The full search will be conducted using
 231 Boolean operators and proximity operators, including wildcards, AND, OR, parentheses,
 232 quotations, and more as per the database used (Table 2).

234 Table 2. Ovid Medline search strategy. Identified search terms with truncated keywords
 235 and MeSH terms for the MEDLINE search via Ovid
 236

	Condition: active or past Venous Leg Ulcers.	Context: Reported levels of health literacy.	Concept: The effect of deficits in health literacy on patient's adherence to compression and effect on healing outcomes.
Text Words	Venous leg Ulcer* Venous ulcer* VLU Venous insufficiency Leg ulcer* Varicose ulcer*	Health Literacy Educat* Health promotion Health Information Health education Nurse-led education	Adher* Concord* Compl* Impact Effect Outcome
Medline	MeSH: Exp Leg Ulcer/	MeSH: Program Evaluation Exp Nursing Research Health education/ or consumer health information/ or health literacy/ or health promotion/ or healthy people programs/ or patient education as topic/ or teach-back communication/	MeSH: Attitude to health/ or health knowledge, attitudes, practice/ or "treatment adherence and compliance"/ or "patient acceptance of health care"/ or patient compliance/Recurrence treatment outcome/ or treatment failure/

		Health facilities/ or hospital units/ or hospitals/ or hospitals, community/ or hospitals, general/ or hospitals, high-volume/ or hospitals, low-volume/ or exp hospitals, private/ or exp hospitals, public/ or exp hospitals, rural/ or exp residential facilities/ or health services/ or exp community health services/ or health services for the aged/ or exp nursing care/ or exp nursing services/ or preventive health services/ or exp rural health services/	Wound Healing Secondary Prevention Self Care Stockings, Compression
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238 **Stage 3: study selection**

239 We will limit our search to papers published in English from January 2000 to December
 240 2020. Other languages will be excluded because the concept of health, and thus, the
 241 concept of health literacy, varies across languages (see (56, 57) for examples). Health
 242 literacy studies will be broadly defined to include studies that sought to assess specific
 243 (i.e., VLU-related) or general health knowledge (i.e., where to find general health
 244 information). This criterion is deliberately broad, as preliminary searches suggest there is
 245 scant literature on this topic. Our study selection will be guided by the following
 246 inclusion criteria:

- 247 Patients – patients with a current or previous VLU.
- 248 Settings – outpatient, community, home care, and inpatient care settings where
 249 VLU is managed.
- 250 Studies – peer reviewed reviews and studies (qualitative and quantitative)
 251 including randomized controlled trials, cohort, case control, quasi-experimental,
 252 cross-sectional, qualitative studies, literature reviews, scoping review guidelines,
 253 policies and protocols.
- 254 Studies that describe knowledge or education or general HL OR an intervention
 255 on this with measures at baseline/control group OR a domain relevant to VLU
 256 knowledge change will be included. Dependent variables include pre-post
 257 knowledge change OR pre-post change in general health literacy, OR description
 258 of health literacy at that state. For our secondary questions, dependent variables
 259 examined will be adherence to exercise recommendations OR adherence to
 260 compression in response to a VLU, or the healing rates of those with VLUs.

261 The following exclusion criteria will apply:

- 262 Patients – no diagnosis of VLU. Exclusion of diabetic foot ulcers, pressure ulcers,
 263 pressure injuries, vascular insufficiency.
- 264 Settings – no non-health care settings (e.g., mail out surveys at home)

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3 265 Studies – narrative reviews, opinions, commentary, conference proceedings.
4 266 Studies that did not examine knowledge, education or general HL and its
5 267 relationship with compression adherence will be excluded.
6
7 268 Selection of sources and evidence will take place in four stages.
8 269 Step A – initial retrieval, which will be performed by one researcher.
9 270 Step B – title screen. Titles that closely meet research aims will be retained. This step
10 271 will be performed by one researcher.
11 272 Step C – abstract screen. Abstracts will be retained if applicable to research aims.
12 273 This step will be performed by two researchers.
13 274 Step D – full text review. Articles retained if they comply with inclusion and
14 275 exclusion criteria. This will be performed by all authors of the research team. The
15 276 numbers of retrieved, assessed, excluded and retained articles will be documented
16 277 using a PRISMA flowchart (template in Figure 1).
17
18 278 Within this step, we will first pilot a sample of 10 studies to ensure that our methods are
19 279 robust, following to Stage 4, then re-running a full search again.

21 280 **Stage 4: charting the data**

22 281 An Excel spreadsheet and/or Covidence will be utilised to chart the data. This database
23 282 will record the title and year of the publication, authors, study location, intervention type,
24 283 study population, aims of the study, overview of methods, outcome measures and results.
25
26 284 Duplicates will be removed via Endnote’s duplicate detecting function.

27 28 285 **Stage 5: collating, summarising and reporting the results**

29 286 Full texts that are retained will undergo study quality assessment and critical appraisal in
30 287 order to determine the applicability of findings to clinical practice. We will use the CASP
31 288 (Critical Skills Appraisal Program)(58). Retained articles will be examined for any
32 289 qualitative or quantitative descriptions. Findings will be presented in a table that outlines
33 290 the study type, year the study was undertaken, sample size, study location, and patient
34 291 characteristics.

35
36 292 In order to assess the first research question, we will examine each study against
37 293 two types of HL: general HL (knowledge or skills) and VLU specific HL (knowledge or
38 294 skills). Findings and critical appraisal of the included articles will be provided in a
39 295 summary of findings and reported in CASP evidence profile table. This table will indicate
40 296 whether the paper suggested the majority of their sample lacked HL (general or specific).
41 297 We anticipate that there will be a highly heterogeneous definition of HL in these papers,
42 298 meaning that authors will be required to use their judgements as to whether or not the
43 299 paper is relevant, as a degree of simplification will be needed. All entries will be checked
44 300 by two authors. The lead author will resolve disagreements (if any) independently.

45
46 301 We aim to identify research gaps in the field of VLU treatments by displaying a
47 302 possible deficit in HL, which translates to lower abilities to adhere to self-management in
48 303 the form of compression and exercise. The findings are also expected to yield a number
49 304 of ways HL deficits in VLU patients can be addressed, thereby adding to care and
50 305 improving standards of care.

51 52 53 306 **Stage 6: Consultation—Patient and public involvement**

54 307 This scoping review is the first phase in a multistage research programme aimed at
55 308 developing a feasibility exercise program as an adjunct to compression intervention for

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3 309 patients with VLUs. During the consultation phase, we will discuss with people with
4 310 VLUs and their families and caregivers from an established Consumer Wounds Group
5 311 whether the results of the scoping review reflect their needs. The consultation process
6 312 will take place at the time of a regular consumer group meeting. Data will be gathered
7 313 using a group interview and Delphi methods. We will map the evidence and identify
8 314 research gaps and report on compression and exercise treatments by investigating HL,
9 315 which translates to lower abilities to adhere to self-management in the form of
10 316 compression and exercise.
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12 317

14 318 **ETHICS AND DISSEMINATION**

15 319 All articles will be sourced from publicly available platforms. As such, this scoping
16 320 review will not require ethical approval. The findings from the scoping review will be
17 321 reported in a separate article and submitted to an open-access peer reviewed journal. The
18 322 results of this paper will provide an outline of the literature, which will be used to inform
19 323 future research into HL in patients with VLU. To facilitate knowledge translation and our
20 324 findings, we will liaise with Consumer Wounds Group. The published protocol and final
21 325 review will be promoted through social media platforms including Twitter and LinkedIn.
22 326 We will submit the final review at National and International Wound and Health
23 327 professional Conferences.
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29 330 **Figure legend**

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31 331 Figure1. PRISMA Flowchart
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References

1. (WHO) WHO. International classification of diseases for mortality and morbidity statistics
2. Domingues EAR, Kaizer UAO, Lima MHM. Effectiveness of the strategies of an orientation programme for the lifestyle and wound - healing process in patients with venous ulcer: A randomised controlled trial. *International wound journal*. 2018;15(5):798-806.
3. Graves N, Zheng H. The prevalence and incidence of chronic wounds: A literature review. . *Wound Practice & Research: Journal of the Australian Wound Management Association*. 2014;22(1):4-12.
4. Xie T, Ye J, Rerkasem K, Mani R. The venous ulcer continues to be a clinical challenge: an update. *Burns & trauma*. 2018;6(1).
5. Meulendijks AM, Franssen WMA, Schoonhoven L, Neumann HAM. A scoping review on Chronic Venous Disease and the development of a Venous Leg Ulcer: The role of obesity and mobility. *J Tissue Viability*. 2020;29(3):190-6. Epub 2019/11/02. doi: 10.1016/j.jtv.2019.10.002. PubMed PMID: 31668667.
6. Weller CD, Team V, Ivory JD, Crawford K, Gethin G. ABPI reporting and compression recommendations in global clinical practice guidelines on venous leg ulcer management: A scoping review. *Int Wound J*. 2019;16(2):406-19. Epub 2018/11/30. doi: 10.1111/iwj.13048. PubMed PMID: 30485668.
7. Pérez MB, López - Casanova P, Lavín RS, Torre HGdl, Verdú - Soriano J. Recent Reports from University of Alicante Highlight Findings in Leg Ulcers [Epidemiology of venous leg ulcers in primary health care: Incidence and prevalence in a health centre-A time series study (2010-2014)] Citation metadata. *International Wound Journal*. 2018;16(1).
8. Jockenhöfer F, Gollnick H, Herberger K, Isbary G, Renner R, Stücker M, et al. Aetiology, comorbidities and cofactors of chronic leg ulcers: retrospective evaluation of 1 000 patients from 10 specialised dermatological wound care centers in Germany. *International wound journal*. 2016;13(5):821-8.
9. Thistlethwaite KR, Finlayson KJ, Cooper PD, Brown B, Bennett MH, Kay G, et al. The effectiveness of hyperbaric oxygen therapy for healing chronic venous leg ulcers: A randomized, double - blind, placebo - controlled trial. *Wound Repair and Regeneration*. 2018;26(4):324-31.
10. Finlayson KJ, Parker CN, Miller C, Gibb M, Kapp S, Ogrin R, et al. Predicting the likelihood of venous leg ulcer recurrence: The diagnostic accuracy of a newly developed risk assessment tool. *Int Wound J*. 2018;15(5):686-94. Epub 2018/03/15. doi: 10.1111/iwj.12911. PubMed PMID: 29536629.
11. Santler B, Goerge T. Chronic venous insufficiency—a review of pathophysiology, diagnosis, and treatment. *JDDG: Journal der Deutschen Dermatologischen Gesellschaft*. 2017;15(5):538-56.
12. Weller C, Ademi Z, Makarounas-Kirchmann K, Stoelwinder J. Economic evaluation of compression therapy in venous leg ulcer randomised controlled trials: A systematic review. *Wound Practice & Research: Journal of the Australian Wound Management Association*. 2012;20(1):21.

- 1
2
3 379 13. Cheng Q, Gibb M, Graves N, Finlayson K, Pacella RE. Cost-effectiveness
4 380 analysis of guideline-based optimal care for venous leg ulcers in Australia. *BMC Health*
5 381 *Serv Res.* 2018;18(1):421. Epub 2018/06/09. doi: 10.1186/s12913-018-3234-3. PubMed
6 382 PMID: 29880046; PubMed Central PMCID: PMC5992639.
- 8 383 14. Nussbaum SR, Carter MJ, Fife CE, DaVanzo J, Haught R, Nusgart M, et al. An
9 384 Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic
10 385 Nonhealing Wounds. *Value Health.* 2018;21(1):27-32. Epub 2018/01/07. doi:
11 386 10.1016/j.jval.2017.07.007. PubMed PMID: 29304937.
- 13 387 15. Tricco AC, Lillie E, Zarin W, O'Brien K, Colquhoun H, Kastner M, et al. A
14 388 scoping review on the conduct and reporting of scoping reviews. *BMC medical research*
15 389 *methodology.* 2016;16(1):15.
- 16 390 16. Ruseckaite R, Richards C, Rutherford C, Team V, Turnour L, Franks P, et al. A
17 391 conceptual framework of patient-reported outcomes in people with venous leg ulcers.
18 392 *Wound Repair Regen.* 2020;28(3):355-63. Epub 2019/12/04. doi: 10.1111/wrr.12787.
19 393 PubMed PMID: 31794080.
- 21 394 17. Cheng Q, Kularatna S, Lee XJ, Graves N, Pacella RE. Comparison of EQ-5D-5L
22 395 and SPVU-5D for measuring quality of life in patients with venous leg ulcers in an
23 396 Australian setting. *Qual Life Res.* 2019;28(7):1903-11. Epub 2019/02/20. doi:
24 397 10.1007/s11136-019-02128-6. PubMed PMID: 30778889.
- 25 398 18. Barnsbee L, Cheng Q, Tulleners R, Lee X, Brain D, Pacella R. Measuring costs
26 399 and quality of life for venous leg ulcers. *International wound journal.* 2019;16(1):112-21.
- 28 400 19. Pacella R, Tulleners R, Cheng Q, Burkett E, Edwards H, S Y, et al. Solutions to
29 401 the chronic wounds problem in Australia: a call to action. *Wound practice and research.*
30 402 2018;26(2):84-98.
- 31 403 20. Australian Wound Management Association Inc., New Zealand Wound Care
32 404 Society Inc. Australian and New Zealand Practice Guideline for Prevention and
33 405 Management of Venous Leg Ulcers. 2011 October 2011. Report No.
- 34 406 21. Team V, Chandler PG, Weller CD. Adjuvant therapies in venous leg ulcer
35 407 management: A scoping review. *Wound Repair Regen.* 2019;27(5):562-90. Epub
36 408 2019/04/27. doi: 10.1111/wrr.12724. PubMed PMID: 31025794.
- 38 409 22. Australian Wound Management Association. KPMG Health Econ report: An
39 410 economic evaluation of compression therapy for venous leg ulcers. Canberra: Australian
40 411 Wound Management Association, 2013.
- 41 412 23. Andriessen A, Apelqvist J, Mosti G, Partsch H, Gonska C, Abel M. Compression
42 413 therapy for venous leg ulcers: risk factors for adverse events and complications,
43 414 contraindications - a review of present guidelines. *J Eur Acad Dermatol Venereol.*
44 415 2017;31(9):1562-8. Epub 2017/06/12. doi: 10.1111/jdv.14390. PubMed PMID:
45 416 28602045.
- 47 417 24. O'Meara S, Cullum N, Nelson E, Dumville J. Compression for venous leg ulcers.
48 418 *Cochrane Database of Systematic Review.* 2013(11).
- 49 419 25. Team V, Chandler PG, Weller CD. Adjuvant therapies in venous leg ulcer
50 420 management: a scoping review. *Wound Repair and Regeneration.* 2019;27(5):562-90.
- 51 421 26. Klonizakis M, Tew G, Gumber A, Crank H, King B, Middleton G, et al.
52 422 Supervised exercise training as an adjunct therapy for venous leg ulcers: a randomized
53 423 controlled feasibility trial. *British Journal of Dermatology.* 2018;178(5):1072-82.

- 1
2
3 424 27. Jull A, Slark J, Parsons J. Prescribed Exercise With Compression vs Compression
4 425 Alone in Treating Patients With Venous Leg Ulcers: A Systematic Review and Meta-
5 426 analysis. *JAMA Dermatol*. 2018;154(11):1304-11. Epub 2018/10/05. doi:
6 427 10.1001/jamadermatol.2018.3281. PubMed PMID: 30285080; PubMed Central PMCID:
7 428 PMC6248128.
- 8 429 28. Orr L, Klement KA, McCrossin L, O'Sullivan Drombolis D, Houghton PE,
9 430 Spaulding S, et al. A Systematic Review and Meta-analysis of Exercise Intervention for
10 431 the Treatment of Calf Muscle Pump Impairment in Individuals with Chronic Venous
11 432 Insufficiency. *Ostomy Wound Manage*. 2017;63(8):30-43. Epub 2017/09/06. doi:
12 433 10.25270/owm.2017.08.3043. PubMed PMID: 28873064.
- 13 434 29. Franks PJ, Barker J, Collier M, Gethin G, Haesler E, Jawien A, et al. Management
14 435 of patients with venous leg ulcers: challenges and current best practice. *Journal of wound*
15 436 *care*. 2016;25(Sup6):S1-S67.
- 16 437 30. Gethin G, Probst S, Stryja J, Christiansen N, Price P. Evidence in Person-Centred
17 438 Care in Chronic Wound Care: A systematic Review and Recommendations for Practice.
18 439 *Journal of wound care*. in Press.
- 19 440 31. Boxall SL, Carville K, Leslie GD, Jansen S. Compression bandaging:
20 441 Identification of factors contributing to non-concordance. *Wound Practice & Research:*
21 442 *Journal of the Australian Wound Management Association*. 2019;27(1):6.
- 22 443 32. Yamashita T, Kart CS. Is diabetes - specific health literacy associated with
23 444 diabetes - related outcomes in older adults? *Journal of diabetes*. 2011;3(2):138-46.
- 24 445 33. Muldoon J. Compression hosiery for venous conditions: a literature review.
25 446 *Journal of Community Nursing*. 2019;33(4).
- 26 447 34. Sørensen K, Pelikan JM, Röthlin F, Ganahl K, Slonska Z, Doyle G, et al. Health
27 448 literacy in Europe: comparative results of the European health literacy survey (HLS-EU).
28 449 *European Journal of Public Health*. 2015;25(6):1053-8.
- 29 450 35. Shi C, Dumville JC, Cullum N. Compression bandages or stockings versus no
30 451 compression for treating venous leg ulcers. *Cochrane Database of Systematic Reviews*.
31 452 2019(8). doi: 10.1002/14651858.CD013397. PubMed PMID: CD013397.
- 32 453 36. Welfare AIOHa. Australia's health 2018. Australia's health series no. 16. AUS
33 454 221. Canberra: AIHW: 2018.
- 34 455 37. Baker DW, Wolf MS, Feinglass J, Thompson JA. Health literacy, cognitive
35 456 abilities, and mortality among elderly persons. *Journal of general internal medicine*.
36 457 2008;23(6):723-6.
- 37 458 38. Yamashita T, Bardo AR, Liu D, Cummins PA. Literacy, numeracy, and health
38 459 information seeking among middle-aged and older adults in the United States. *Journal of*
39 460 *aging and health*. 2020;32(1):33-41.
- 40 461 39. Turner AM, Osterhage KP, Taylor JO, Hartzler AL, Demiris G, editors. A Closer
41 462 Look at Health Information Seeking by Older Adults and Involved Family and Friends:
42 463 Design Considerations for Health Information Technologies. *AMIA Annual Symposium*
43 464 *Proceedings*; 2018: American Medical Informatics Association.
- 44 465 40. Chaudhuri S, Le T, White C, Thompson J, Demiris G. Examining health
45 466 information-seeking behaviors of older adults. *Computers, informatics, nursing*.
46 467 2013;31(11):547.
- 47
48
49
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53
54
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56
57
58
59
60

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2
3 468 41. Chase SK, Melloni M, Savage A. A forever healing: the lived experience of
4 469 venous ulcer disease. *J Vasc Nurs*. 1997;15(2):73-8. Epub 1997/06/01. doi:
5 470 10.1016/s1062-0303(97)90004-2. PubMed PMID: 9238945.
- 6 471 42. Shanley E, Moore Z, Patton D, O'Connor T, Nugent L, Budri AM, et al. Patient
7 472 education for preventing recurrence of venous leg ulcers: a systematic review. *J Wound*
8 473 *Care*. 2020;29(2):79-91. Epub 2020/02/15. doi: 10.12968/jowc.2020.29.2.79. PubMed
9 474 PMID: 32058853.
- 10 475 43. Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health
11 476 literacy and health outcomes: an updated systematic review. *Ann Intern Med*.
12 477 2011;155(2):97-107. Epub 2011/07/20. doi: 10.7326/0003-4819-155-2-201107190-
13 478 00005. PubMed PMID: 21768583.
- 14 479 44. MacLeod S, Musich S, Gulyas S, Cheng Y, Tkatch R, Cempellin D, et al. The
15 480 impact of inadequate health literacy on patient satisfaction, healthcare utilization, and
16 481 expenditures among older adults. *Geriatric Nursing*. 2017;38(4):334-41.
- 17 482 45. Graham S, Brookey J. Do patients understand? *The permanente journal*.
18 483 2008;12(3):67.
- 19 484 46. Walshe C. Living with a venous leg ulcer: a descriptive study of patients'
20 485 experiences. *Journal of advanced nursing*. 1995;22(6):1092-100.
- 21 486 47. Chase SK, Whittemore R, Crosby N, Freney D, Howes P, Phillips TJ. Living with
22 487 chronic venous leg ulcers: a descriptive study of knowledge and functional health status.
23 488 *J Community Health Nurs*. 2000;17(1):1-13. Epub 2000/04/25. doi:
24 489 10.1207/S15327655JCHN1701_01. PubMed PMID: 10778025.
- 25 490 48. Probst S, Sechaud L, Bobbink P, Skinner MB, Weller CD. The lived experience
26 491 of recurrence prevention in patients with venous leg ulcers: An interpretative
27 492 phenomenological study. *J Tissue Viability*. 2020;29(3):176-9. Epub 2020/01/25. doi:
28 493 10.1016/j.jtv.2020.01.001. PubMed PMID: 31974010.
- 29 494 49. CLARKE C, WHITMORE L, WEBB A. Patient education pictorial boards:
30 495 improving patients' understanding of venous leg ulcer and compression therapy. *Wounds*
31 496 *UK*. 2020;16(2).
- 32 497 50. Margolis DJ, Hampton M, Hoffstad O, Malay DS, Thom S. Health literacy and
33 498 diabetic foot ulcer healing. *Wound Repair Regen*. 2015;23(3):299-301. Epub 2015/04/30.
34 499 doi: 10.1111/wrr.12311. PubMed PMID: 25923608; PubMed Central PMCID:
35 500 PMC4519401.
- 36 501 51. Lael-Monfared E, Tehrani H, Moghaddam ZE, Ferns GA, Tatari M, Jafari A.
37 502 Health literacy, knowledge and self-care behaviors to take care of diabetic foot in low-
38 503 income individuals: Application of extended parallel process model. *Diabetes Metab*
39 504 *Syndr*. 2019;13(2):1535-41. Epub 2019/07/25. doi: 10.1016/j.dsx.2019.03.008. PubMed
40 505 PMID: 31336518.
- 41 506 52. Boren SA. A review of health literacy and diabetes: opportunities for technology.
42 507 *J Diabetes Sci Technol*. 2009;3(1):202-9. Epub 2010/01/05. doi:
43 508 10.1177/193229680900300124. PubMed PMID: 20046666; PubMed Central PMCID:
44 509 PMC2769840.
- 45 510 53. Xu XY, Leung AYM, Chau PH. Health literacy, self-efficacy, and associated
46 511 factors among patients with diabetes. *HLRP: Health Literacy Research and Practice*.
47 512 2018;2(2):e67-e77.

- 1
2
3 513 54. Pham MT, Rajić A, Greig JD, Sargeant JM, Papadopoulos A, McEwen SA. A
4 514 scoping review of scoping reviews: advancing the approach and enhancing the
5 515 consistency. *Research synthesis methods*. 2014;5(4):371-85.
6 516 55. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al.
7 517 PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation.
8 518 *Annals of internal medicine*. 2018;169(7):467-73.
9 519 56. Choi TS, Walker KZ, Ralston RA, Palermo C. Diabetes education needs of
10 520 Chinese Australians: A qualitative study. *Health Education Journal*. 2015;74(2):197-208.
11 521 57. Walker C, Weeks A, McAvoy B, Demetriou E. Exploring the role of self -
12 522 management programmes in caring for people from culturally and linguistically diverse
13 523 backgrounds in Melbourne, Australia. *Health Expectations*. 2005;8(4):315-23.
14 524 58. Singh J. Critical appraisal skills programme. *Journal of pharmacology and*
15 525 *Pharmacotherapeutics*. 2013;4(1):76.
16 526
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22 532
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Authorship

17 570 CW provided substantial contributions to the conception and design of the work, revisited
18 571 it critically for important intellectual content, provided final approval of the submitted
19 572 version and an agreement to be accountable for all aspects of the work in ensuring that
20 573 questions related to the accuracy or integrity of any part of the work are appropriately
21 574 investigated and resolved.
22 575

23 576 VT provided substantial contributions to the conception and design of the work, produced
24 577 the first draft, revisited it critically for important intellectual content, provided final
25 578 approval of the submitted version and an agreement to be accountable for all aspects of
26 579 the work in ensuring that questions related to the accuracy or integrity of any part of the
27 580 work are appropriately investigated and resolved.
28 581

29 582 SP provided substantial contributions to the conception and design of the work, revisited
30 583 it critically for important intellectual content, provided final approval of the submitted
31 584 version and an agreement to be accountable for all aspects of the work in ensuring that
32 585 questions related to the accuracy or integrity of any part of the work are appropriately
33 586 investigated and resolved.
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35 588 GG provided substantial contributions to the conception and design of the work, revisited
36 589 it critically for important intellectual content, provided final approval of the submitted
37 590 version and an agreement to be accountable for all aspects of the work in ensuring that
38 591 questions related to the accuracy or integrity of any part of the work are appropriately
39 592 investigated and resolved.
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41 594 CR provided substantial contributions to the conception and design of the work, produced
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44 597 of the work in ensuring that questions related to the accuracy or integrity of any part of
45 598 the work are appropriately investigated and resolved.
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47 600 JS provided substantial contributions to the conception and design of the work, revisited
48 601 it critically for important intellectual content, provided final approval of the submitted
49 602 version and an agreement to be accountable for all aspects of the work in ensuring that
50 603 questions related to the accuracy or integrity of any part of the work are appropriately
51 604 investigated and resolved.
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4 606 LT provided substantial contributions to the conception and design of the work, revisited
5 607 it critically for important intellectual content, provided final approval of the submitted
6 608 version and an agreement to be accountable for all aspects of the work in ensuring that
7 609 questions related to the accuracy or integrity of any part of the work are appropriately
8 610 investigated and resolved.

9 611
10 612 AB provided substantial contributions to the conception and design of the work,
11 613 produced the first draft, revisited it critically for important intellectual content, provided
12 614 final approval of the submitted version and an agreement to be accountable for all aspects
13 615 of the work in ensuring that questions related to the accuracy or integrity of any part of
14 616 the work are appropriately investigated and resolved.
15 617

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20 619
21 620 Professor Carolina Weller
22 621

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28

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34

35 630 **Conflicts of interest**

36 631 We have read and understood BMJ policy on declaration of interests and declare that we
37 632 have no competing interests.
38

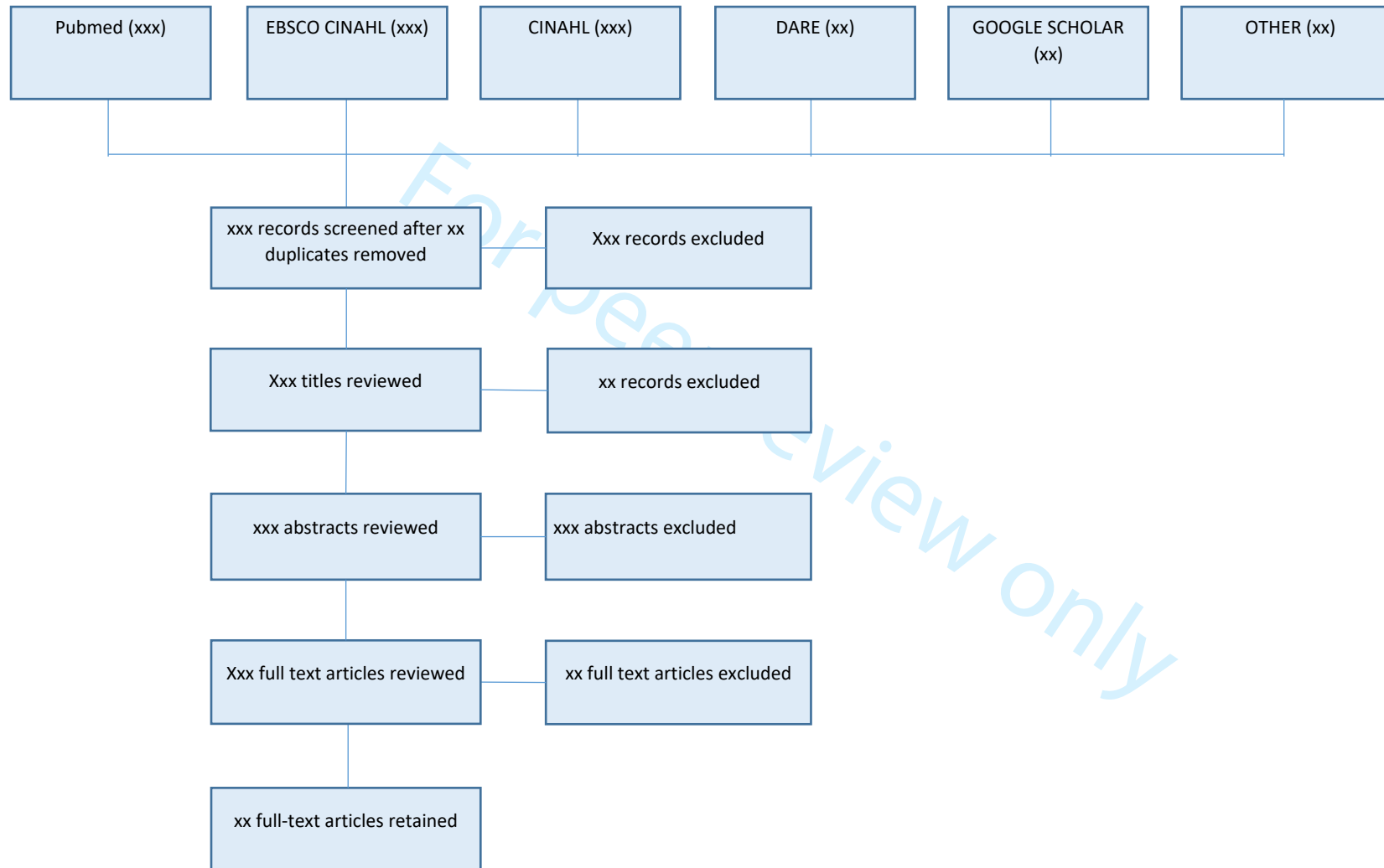
39 633 40 634 **Data statement**

41 635 Not applicable.
42

43 636 **Abbreviations**

44 637 HL: Health Literacy
45 638 VLU: Venous Leg Ulcer
46 639 CVI: Chronic Venous Insufficiency
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Figure 1. PRISMA flowchart



Appendix 1: Search strings for MEDLINE via Ovid

- 1 exp Leg Ulcer/
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 8 2 (venous leg ulcer* or Venous ulcer* or VLU or Venous insufficiency or Leg ulcer* or Varicose
 9 ulcer*).mp. [mp=title, abstract, original title, name of substance word, subject heading word,
 10 floating sub-heading word, keyword heading word, organism supplementary concept word, protocol
 11 supplementary concept word, rare disease supplementary concept word, unique identifier,
 12 synonyms]
 13
 14 3 1 or 2
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 16 4 Program Evaluation/
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 18 5 exp Nursing Research/
 19
 20 6 health education/ or consumer health information/ or health literacy/ or health promotion/ or healthy
 21 people programs/ or patient education as topic/ or teach-back communication/
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 23 7 health facilities/ or hospital units/ or hospitals/ or hospitals, community/ or hospitals, general/ or
 24 hospitals, high-volume/ or hospitals, low-volume/ or exp hospitals, private/ or exp hospitals, public/
 25 or exp hospitals, rural/ or exp residential facilities/ or health services/ or exp community health
 26 services/ or health services for the aged/ or exp nursing care/ or exp nursing services/ or preventive
 27 health services/ or exp rural health services/
 28
 29 8 (Know* adj2 (health or disease or Illness)).mp. [mp=title, abstract, original title, name of substance
 30 word, subject heading word, floating sub-heading word, keyword heading word, organism
 31 supplementary concept word, protocol supplementary concept word, rare disease supplementary
 32 concept word, unique identifier, synonyms]
 33
 34 9 (Health adj2 (educat* or literacy or interest or understanding)).mp. [mp=title, abstract, original title,
 35 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
 36 organism supplementary concept word, protocol supplementary concept word, rare disease
 37 supplementary concept word, unique identifier, synonyms]
 38
 39 10 (Interest* adj2 health interest).mp. [mp=title, abstract, original title, name of substance word, subject
 40 heading word, floating sub-heading word, keyword heading word, organism supplementary concept
 41 word, protocol supplementary concept word, rare disease supplementary concept word, unique
 42 identifier, synonyms]
 43
 44 11 (Information adj2 (dissemination or access or services or technology)).mp. [mp=title, abstract,
 45 original title, name of substance word, subject heading word, floating sub-heading word, keyword
 46 heading word, organism supplementary concept word, protocol supplementary concept word, rare
 47 disease supplementary concept word, unique identifier, synonyms]
 48
 49 12 (Teach* adj materials).mp. [mp=title, abstract, original title, name of substance word, subject
 50 heading word, floating sub-heading word, keyword heading word, organism supplementary concept
 51 word, protocol supplementary concept word, rare disease supplementary concept word, unique
 52 identifier, synonyms]
 53
 54 13 (Health Literacy or Educat* or Health promotion or Nurse-led education).mp. [mp=title, abstract,
 55 original title, name of substance word, subject heading word, floating sub-heading word, keyword
 56 heading word, organism supplementary concept word, protocol supplementary concept word, rare
 57 disease supplementary concept word, unique identifier, synonyms]
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- 14 Recurrence/
- 15 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
- 16 attitude to health/ or health knowledge, attitudes, practice/ or "treatment adherence and compliance"/
or "patient acceptance of health care"/ or patient compliance/ or treatment refusal/
- 17 Recurrence/
- 18 treatment outcome/ or treatment failure/
- 19 Wound Healing/
- 20 Secondary Prevention/
- 21 Self Care/
- 22 Stockings, Compression/
- 23 (Adher* adj2 (compression or self care or self management)).mp. [mp=title, abstract, original title,
name of substance word, subject heading word, floating sub-heading word, keyword heading word,
organism supplementary concept word, protocol supplementary concept word, rare disease
supplementary concept word, unique identifier, synonyms]
- 24 (Concord* adj2 (compression or self care or self management)).mp. [mp=title, abstract, original title,
name of substance word, subject heading word, floating sub-heading word, keyword heading word,
organism supplementary concept word, protocol supplementary concept word, rare disease
supplementary concept word, unique identifier, synonyms]
- 25 (Compl* adj2 (compression or self care or self management)).mp. [mp=title, abstract, original title,
name of substance word, subject heading word, floating sub-heading word, keyword heading word,
organism supplementary concept word, protocol supplementary concept word, rare disease
supplementary concept word, unique identifier, synonyms]
- 26 (Adher* or Concord* or Compl* or Impact or Effect or Outcome or Adher* or Healing or Recur* or
Compress* or self care or Self manag* or health behavio?r*).mp. [mp=title, abstract, original title,
name of substance word, subject heading word, floating sub-heading word, keyword heading word,
organism supplementary concept word, protocol supplementary concept word, rare disease
supplementary concept word, unique identifier, synonyms]
- 27 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26
- 28 3 and 15 and 27

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	1
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	N/A
Authors			
Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1

1	Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	16-17
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3				
4	Amendments			
5				
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7		#4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
8				
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14	Support			
15				
16	Sources	#5a	Indicate sources of financial or other support for the review	17
17				
18	Sponsor	#5b	Provide name for the review funder and / or sponsor	17
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21	Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	N/A
22				
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25	Introduction			
26				
27	Rationale	#6	Describe the rationale for the review in the context of what is already known	4
28				
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31	Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
32				
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36	Methods			
37				
38	Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5-6
39				
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45	Information sources	#9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	8
46				
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52	Search strategy	#10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Table 2 8-9
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1	Study records -	#11a	Describe the mechanism(s) that will be used to manage	9-10
2	data management		records and data throughout the review	
3				
4	Study records -	#11b	State the process that will be used for selecting studies	9
5	selection process		(such as two independent reviewers) through each phase	
6			of the review (that is, screening, eligibility and inclusion in	
7			meta-analysis)	
8				
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10				
11	Study records -	#11c	Describe planned method of extracting data from reports	10
12	data collection		(such as piloting forms, done independently, in duplicate),	
13	process		any processes for obtaining and confirming data from	
14			investigators	
15				
16				
17				
18	Data items	#12	List and define all variables for which data will be sought	9
19			(such as PICO items, funding sources), any pre-planned	
20			data assumptions and simplifications	
21				
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24	Outcomes and	#13	List and define all outcomes for which data will be sought,	10
25	prioritization		including prioritization of main and additional outcomes,	
26			with rationale	
27				
28				
29	Risk of bias in	#14	Describe anticipated methods for assessing risk of bias of	10
30	individual studies		individual studies, including whether this will be done at the	
31			outcome or study level, or both; state how this information	
32			will be used in data synthesis	
33				
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36	Data synthesis	#15a	Describe criteria under which study data will be	10
37			quantitatively synthesised	
38				
39				
40	Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe	N/A
41			planned summary measures, methods of handling data and	
42			methods of combining data from studies, including any	
43			planned exploration of consistency (such as I ² , Kendall's τ)	
44				
45				
46	Data synthesis	#15c	Describe any proposed additional analyses (such as	N/A
47			sensitivity or subgroup analyses, meta-regression)	
48				
49				
50	Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the	N/A
51			type of summary planned	
52				
53				
54	Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as	N/A
55			publication bias across studies, selective reporting within	
56			studies)	
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1 Confidence in #17 Describe how the strength of the body of evidence will be 10
2 cumulative assessed (such as GRADE)
3 evidence
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8 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with
9 [Penelope.ai](#)
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