

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Health literacy in people with venous leg ulcers: A protocol for scoping review
<b>AUTHORS</b>	Weller, CD; Team, Victoria; Probst, Sebastian; Gethin, Georgina; Richards, Catelyn; Sixsmith, Jane; Turnour, Louise; Bouguettaya, Ayoub

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Todd, Marie NHS Greater Glasgow and Clyde, Lymphoedema
<b>REVIEW RETURNED</b>	23-Nov-2020

<b>GENERAL COMMENTS</b>	This study protocol appears to meet the criteria required by your organisation. The findings will be very valuable in determining approaches to VLU management and contributing to the evidence base.
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<b>REVIEWER</b>	Haynes, Samantha Solent NHS Trust, Tissue Viability Team
<b>REVIEW RETURNED</b>	26-Nov-2020

<b>GENERAL COMMENTS</b>	<p>Thank you for the opportunity to review this very interesting protocol for a scoping review focusing on health literacy in patients with VLU. This is my first peer review for BMJ Open, and I hope my review will be helpful. From my perspective as a clinician, the proposed review is very important as health literacy is an often neglected area in the care of patients with VLU. Health literacy has been recognised as being important in the care of patients with other wound types such as diabetic foot ulcers. Health literacy can have a huge impact on patient's self-management capabilities and this is particularly relevant to patients with VLU, who need to commit to life-long compression therapy and can improve their healing with interventions such as ankle exercises, weight management and stress management.</p> <p>This protocol reads well and generally has a clear message. The study rationale justifies the need for the scoping review. I wonder if the evidence about health literacy and diabetic foot ulcer healing could also be included in the discussion about health literacy affecting health outcomes (line 172)? For instance:- Margolis DJ, Hampton M, Hoffstad O, Malay DS, Thom S Health literacy and diabetic foot ulcer healing Wound Repair Regen. 2015 May-Jun;23(3):299-301. doi: 10.1111/wrr.12311. Lael-Monfared, Elaheh ; Tehrani, Hadi ; Moghaddam, Zahra Esmati ; Ferns, Gordon A; Tatari, Maryam ; Jafari, Alireza Health literacy, knowledge and self-care behaviours to take care of diabetic foot in low-income individuals: Application of extended</p>
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	<p>parallel process model Diabetes &amp; metabolic syndrome clinical research &amp; reviews, 2019-03, Vol.13 (2), p.1535-1541</p> <p>It may be useful to clarify the stated aims. In the abstract it states that 'the scoping review aims to develop a search strategy to scope what HL interventions exist for people with VLU'. However in the body of the protocol, the aim reads slightly differently - 'to scope the research examining the level of HL in VLU, how this level may link to self-management behaviours (particularly exercise and compression adherence), and their leg ulcer healing generally.'</p> <p>The aim in the body of the protocol relates clearly to the identified research questions. The objective of developing clinical practice guidelines and an assessment tool is of particular interest to me as a clinician. The use of an assessment tool and clinical practice guidelines to enable the provision of education according to patient's level of health literacy has the potential to improve the outcomes of patients with VLU.</p> <p>The method of identifying the relevant studies is comprehensive. The inclusion and exclusion criteria are clearly defined and allow for a broad range of studies from a variety of settings that will hopefully provide some rich data. I would suggest that there is a planned piloting of the data extraction/charting included in the protocol.</p> <p>The inclusion of a consultation phase involving patients with VLU and their family members is excellent. It would be interesting to understand how this consultation process will happen. What methods will be employed to gather the data from these individuals during the consultation phase?</p> <p>Just a few other points for consideration:-</p> <ul style="list-style-type: none"> <li>• Line 102, the sentence 'Of these, physical...' could be reworded into two sentences</li> <li>• Line 165 sentence 'One educational intervention recent study...' requires rewording</li> <li>• Line 172 Line 304 sentence 'To ensure that our needs...' could be reworded into two sentences.</li> </ul> <p>Thank you again for providing me with the opportunity to review this protocol for a scoping review. This is a much needed area of study and will be an important contribution to the care of people with VLU.</p>
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## VERSION 1 – AUTHOR RESPONSE

Response to Reviewer: 1

- This study protocol appears to meet the criteria required by your organisation. The findings will be very valuable in determining approaches to VLU management and contributing to the evidence base.

We appreciate Reviewer 1's work. Thank you.

Response to Reviewer 2

- Thank you for the opportunity to review this very interesting protocol for a scoping review focusing on health literacy in patients with VLU. This is my first peer review for BMJ Open, and I hope my review will be helpful. From my perspective as a clinician, the proposed review

is very important as health literacy is an often-neglected area in the care of patients with VLU. Health literacy has been recognised as being important in the care of patients with other wound types such as diabetic foot ulcers. Health literacy can have a huge impact on patient's self-management capabilities and this is particularly relevant to patients with VLU, who need to commit to life-long compression therapy and can improve their healing with interventions such as ankle exercises, weight management and stress management.

This is true. We thank the reviewer for this comment, as we agree.

- This protocol reads well and generally has a clear message. The study rationale justifies the need for the scoping review. I wonder if the evidence about health literacy and diabetic foot ulcer healing could also be included in the discussion about health literacy affecting health outcomes (line 172)? For instance:- Margolis DJ, Hampton M, Hoffstad O, Malay DS, Thom S Health literacy and diabetic foot ulcer healing Wound Repair Regen. 2015 May-Jun;23(3):299-301. doi: 10.1111/wrr.12311.

Lael-Monfared, Elaheh ; Tehrani, Hadi ; Moghaddam, Zahra Esmati ; Ferns, Gordon A; Tatari, Maryam ; Jafari, Alireza Health literacy, knowledge and self-care behaviours to take care of diabetic foot in low-income individuals: Application of extended parallel process model Diabetes & metabolic syndrome clinical research & reviews, 2019-03, Vol.13 (2), p.1535-1541

Thank you for these suggestions. We added in both these studies, stating:

For example, two studies on diabetic foot ulcers have found that lower levels of HL were linked to inappropriate self-care and delayed wound healing.

- It may be useful to clarify the stated aims. In the abstract it states that 'the scoping review aims to develop a search strategy to scope what HL interventions exist for people with VLU'. However, in the body of the protocol, the aim reads slightly differently - 'to scope the research examining the level of HL in VLU, how this level may link to self-management behaviours (particularly exercise and compression adherence), and their leg ulcer healing generally.' The aim in the body of the protocol relates clearly to the identified research questions. The objective of developing clinical practice guidelines and an assessment tool is of particular interest to me as a clinician. The use of an assessment tool and clinical practice guidelines to enable the provision of education according to patient's level of health literacy has the potential to improve the outcomes of patients with VLU.

Thank you for highlighting this. We have replaced the aim in the abstract:

"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."

- The method of identifying the relevant studies is comprehensive. The inclusion and exclusion criteria are clearly defined and allow for a broad range of studies from a variety of settings that will hopefully provide some rich data. I would suggest that there is a planned piloting of the data extraction/charting included in the protocol.

Thank you for this suggestion. We have added the following sentence:

Line 228: Within this step, we will first pilot a sample of 10 studies to ensure our that our methods are robust, following to Stage 4, then re-running a full search again.

- The inclusion of a consultation phase involving patients with VLU and their family members is excellent. It would be interesting to understand how this consultation process will happen. What methods will be employed to gather the data from these individuals during the consultation phase?

Thank you, we clarified this aspect – Lines 314-316.

The consultation process will take place at the time of regular consumer group meeting. Data will be gathered using a group interview and Delphi methods.

Just a few other points for consideration: -

- Line 102, the sentence 'Of these, physical...' could be reworded into two sentences
- Line 165 sentence 'One educational intervention recent study...' requires rewording
- Line 172 Line 304 sentence 'To ensure that our needs...' could be reworded into two sentences.

We have made all these modifications:

Line 102 (Now 104-108): Split into two sentences.

Of these, physical activity has received mixed evidence on its efficacy when combined with compression. (26, 27) However, it is still generally recommended as the most recent evidence suggests that if patients adhere to physical activity recommendations, venous insufficiency can improve, thus possibly improve healing and reducing the risk of recurrence.(27, 28)

Line 165 (Now 167-170) Rewritten. Now reads as:

One educational intervention study (N=20) indicated that specific HL in VLU is poor, but also demonstrated that there is utility in improving HL in VLU patients. The authors reported that patients felt more confident in VLU management after the educational intervention.(49)

Line 172: Split into three sentences. Now reads as

During the consultation phase, we will discuss with people with VLUs and their families and caregivers from an established Consumer Wounds Group whether the results of the scoping review reflect their needs. The consultation process will take place at the time of a regular consumer group meeting.

- Thank you again for providing me with the opportunity to review this protocol for a scoping review. This is a much-needed area of study and will be an important contribution to the care of people with VLU.

We would like to once again thank both reviewers for their positivity.