

Improving Adherence to Wearing Compression Stockings for Chronic Venous Insufficiency and Venous Leg Ulcers: A Scoping Review

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Purpose: Patient adherence to wearing compression stockings in the management of chronic venous insufficiency (CVI) and venous leg ulcers (VLUs) is low. Poor adherence with compression stockings contributes to recurrence and impaired healing of VLUs. As such, the purpose of this review was to report on the scientific evidence related to adherence and explore modifiable factors which impact adherence with compression stockings.

Methods: A systematic search was conducted from inception to 31 October 2019. Following the PRISMA-ScR Checklist, PubMed, Medline, CINAHL, Cochrane, Embase, OT Seeker and Web of Science were explored using search terms: compression/compression stocking/compression garment/compression sock/stockings/garments and adherence/compliance/concordance.

Results: We identified 2613 papers of which 125 full text papers were assessed for eligibility and 69 met inclusion criteria. Papers were grouped and charted by concepts relevant to the research questions and narratively synthesized. Several dominant themes emerged, and a conceptual framework was developed incorporating modifiable variables, adherence itself, and outcomes related to adherence. Specifically considering interventions to improve adherence, only five of 14 randomized controlled trials were able to demonstrate improvements in adherence through unidimensional approaches. All nine of the case studies/series demonstrated a positive impact on adherence, eight of which described a personalized multidimensional approach. A lack of consensus around defining, measuring, and quantifying adherence with compression stockings was identified, resulting in wide variation in reported adherence rates.

Conclusion: Inconsistency in the definition and measurement of adherence limits meaningful interpretation of the literature. No individual intervention has consistently demonstrated improved adherence. Multidimensional interventions show promise but require further investigation with high-quality trials. Improving adherence appears to improve health outcomes in VLU /CVI populations but there is a lack of information directly linking improved adherence with cost outcomes.

Trial Registration: Open Science Framework: ACTRN12620000544976p.

Keywords: scoping review, compression stockings, adherence, leg ulcers, chronic venous insufficiency

Plain Language Summary

Venous leg ulcers are open sores in the skin of the lower legs which are typically painful, heal slowly and expensive to treat. Wearing compression stockings is the best treatment to heal and prevent ulcers, but some patients do not wear their stockings as much as they

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should. That is, adherence to the recommended treatment is low. A review of the literature was conducted to find out what is known about this topic and what information is missing. We discovered that researchers have attempted to improve adherence with wearing compression stockings but are still exploring ways to improve adherence where each person has different reasons (barriers) for not wearing them. Higher adherence rates have been found where authors have identified individual barriers and then developed personalized and multidimensional interventions. However, this can be difficult when dealing with large numbers of people. Interventions that can be used on a large population that firstly identifies patients' barriers before developing personalized treatment plans are required. There is little consistency in the way adherence is scored or measured and to enable future researchers to compare studies, it would be beneficial to have a consistent way to score and measure adherence.

Background

Venous leg ulcers (VLUs) are open wounds in the skin that occur due to high blood pressure inside the leg.¹⁻³ Most often seen in older adults who have chronic venous insufficiency (CVI), they follow a natural cycle of prolonged healing and recurrence²⁻⁴ and may become chronic, persisting for many years.⁴ VLUs can lead to distress, loss of function and pain.⁴⁻⁶ International prevalence studies estimate that between 1.5 and 3.0 per 1000 people have active leg ulcers.⁴ Medically prescribed compression stockings are the gold standard in the long-term management of CVI, to heal and prevent VLUs.^{1,7-9} Compression reduces vein distension, assists calf musculature to pump blood against gravity and lessens oedema.¹⁰ VLUs are more likely to recur when patients do not comply with compression treatment.¹¹ Adherence rates of 12% to 52%¹² indicate many patients do not reap the health benefits of compression therapy. Poor adherence also has large financial implications.¹³ In Australia it is estimated that the cost of healing a VLU could be reduced from AUSD\$10743 to \$3883 per patient if compression stockings were used as prescribed.¹⁴ Further, if compression stockings were provided to all affected individuals nationally it would cost an additional AUSD\$270 million but save AUSD\$1.4 billion over five years.¹⁵

Extensively documented in the literature, multiple non-modifiable barriers exist to the wearing of compression stockings, including person-related factors, such as age, educational background, and cognition as well as environmental factors like climate, and income.^{4,16} Acknowledging that while there is potential for these to

change, for example relocating to a cooler climate, these variables are largely fixed at the time of any patient intervention. On the other hand, other variables are more easily modifiable at the time of intervention and can be addressed by clinicians and researchers, such as stocking type, stocking education and use of assistive devices. Many variables have been described but to date, broad synthesis of the literature pertaining to these factors has not been undertaken.

Improving adherence with compression therapy, presents an opportunity to reduce the personal health burden imposed by VLUs upon patients and benefit wider society economically however, it remains unclear how to do this. A 2016 Cochrane review of interventions to improve adherence to compression therapy in patients with VLUs¹ yielded only three randomized controlled trials (RCTs). They concluded that there was a lack of high-quality trials and uncertainty whether any interventions help. Other reviews on the topic provide some potential insights, despite their inclusion of broader patient groups than VLUs and/or broader adherence domains other than compression therapy. One review¹⁷ was focused on the impact of compression class in post-thrombotic and VLU populations and found that lower compression classes showed higher adherence. Another¹⁸ took a more multidimensional perspective by investigating patient reasons for nonadherence to compression therapy, lifestyle advice and exercises. They concluded that patient-perceived pain, and professional advice both influenced adherence and suggested a multidimensional approach is needed. These authors^{11,18} did not synthesize data pertaining to the efficacy of interventions targeting adherence. One older literature review of studies up to 2005, synthesized a variety of study designs of interventions for adherence and revealed some support for a multidimensional approach to improving adherence, but again included the broader adherence criteria of compression, leg exercises and elevation.¹¹ Consequently, to ensure clinical practice is up to date and research gaps are targeted, a broad and current literature synthesis, specifically regarding adherence to compression therapy in VLUs, is needed.

There is also ambiguity surrounding the definition and measurement of adherence.¹¹ The literature varyingly names adherence as "compliance" or "concordance". In a medical context, these terms indicate the extent to which patients follow the instructions they are given for treatment.¹⁹ In the context of compression wear, the term

“adherence” is preferred, as it implies non-judgement; “a statement of fact rather than of blame attributable to the patient, prescriber or compression treatment”.¹⁷ It has been recommended that adherence should be “defined specifically for the situation, with parameters of acceptable adherence carefully delineated”²⁰ but the literature has suggested a lack of standardization across health behaviors.²⁰

Stocking adherence can exist as a bivariate measure, that is the number of days per week as well as the number of hours per day that compression stockings are worn, yet a lack of consistency exists around the way researchers measure it.²¹ The lack of clarity in agreed-upon definitions and scoring methods may confound the interpretation and generalizability of clinical research results.²² This highlights the need to look broadly across the adherence literature in the VLU and CVI patient group to describe and synthesize adherence definitions and its measurement, to inform the methodological quality of future research.

Therefore, the aim of this scoping review is to report on the scope and breadth of literature relating specifically to VLU and CVI on adherence with compression stockings particularly in relation to interventions, and how the phenomenon is measured and defined. This will be the first scoping review to look specifically at improving adherence to compression therapy in the VLU and CVI population.

Research Questions

1. What factors and interventions have been reported in the literature to attempt to improve compression stocking adherence?
2. How has adherence been defined in the literature and how have adherence rates been reported and measured in the population of VLU and CVI?
3. What is the impact of adherence on patient outcomes?
4. What knowledge gaps currently exist?

Methods

To bring cohesion to the research pool and appreciate the breadth of domains that impact adherence to compression therapy, a scoping literature review was chosen.²³ Due to the exploratory nature of the topic, this approach will allow for collation of information from multidisciplinary bodies of knowledge and allow mapping of key concepts and knowledge gaps.

Protocol

The PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation²⁴ was used. A health librarian and second reviewer supported the process.

A priori protocol was developed and published on the Open Science Framework:

<https://mfr.osf.io/render?url=https://osf.io/egn53/?direct%26mode=render%26action=download%26mode=render>

Design

The design was composed of two phases. Firstly, the search strategy employed Arksey and O'Malley's methodological framework²⁵ using an iterative approach allowing for a comprehensive review designed to identify all relevant literature regardless of study design. Following an analysis of the literature a conceptual framework was then developed, employing Jabareens' methodology²⁶ linking multidisciplinary bodies of knowledge.

Eligibility Criteria

Using a PCC (population/ concept/ context) framework,²⁷ the eligibility criteria were defined as: Population (included the target population of those with VLU or CVI), Concept (including any study that investigated modifiable variables relating to the use of compression stockings either as a direct outcome of a study, as an incidental finding or by comment by an expert, and Context (including any study that were of any study design and date of publication). Included were published articles and conference proceedings in the English language.

Exclusion criteria were studies that a) specifically focused on short-term/time-limited wearing of compression stockings, such as in pregnancy, for the treatment of deep vein thrombosis, “flight socks”, TEDs (Thrombo-Embolus Device), burns and post-vein surgical procedures, b) focused solely on the treatment of lymphoedema, c) looked exclusively at non-modifiable variables (such as climate, cognitive ability, access to stockings, religious or ethnic variables and others), d) were in languages other than English, e) were books, patents, or webpages, f) described compression delivered exclusively via other modalities eg bandaging, wrap systems or intermittent pneumatic pumps, and f) were not available in full text. Those papers that did not meet the criteria were removed. Subsequently, the full texts of the remaining studies were obtained and screened to determine eligibility.

Literature Search

A search of the following electronic bibliographic databases was conducted: Medline, PubMed, CINAHL, Embase, Cochrane, Web of Science, Google Scholar and OT Seeker. The search strategy was peer-reviewed by an expert health librarian. The dates searched were from inception of the database till the final date of the search (25th October 2019). References were downloaded from electronic search engines, inputted into an excel spreadsheet and then transferred to an electronic bibliographic system (ENDNOTE). Terms used in the search were as follows: compression/compression stocking/compression garment/compression sock/stockings/garments and adherence/compliance/concordance. While specifically interested in VLUs, we commenced our search looking at the broader scope of lower limb vascular conditions. The initial search using the MESH terms venous leg ulcers AND chronic venous insufficiency, excluded many relevant articles. When included as an “OR” MESH term, a nonsensical number of articles was identified hence the need to manually assess each article based on the parameters of this review. This enabled us to include papers that may have findings transferable to a broader population. This was then narrowed to include only those with CVI or VLU. Two phases of snowballing occurred to complement our search strategy.

Data Analysis and Synthesis

As the scope and nature of the available evidence was not known in advance, the development of categories and grouping for mapping purposes was developed iteratively as the data was extracted and tabulated. See [Appendix 1](#) for data extraction template. Aligning with Jabareen's methodology,²⁶ data was synthesized narratively by categories defined during the mapping process, to allow flexibility in development of themes to bring coherence to the data. A conceptual framework was logically constructed, around the theme of adherence.^{26,28} Using bibliographic analyses, papers were grouped by year of publication and further categorized using the Levels of Evidence Pyramid.²⁹ As we were particularly interested to find out if any interventions have been able to influence adherence, RCTs and case reports/series were further analyzed to address the research questions. An analysis was conducted using frequencies supplemented by a narrative review. For consistency, data about adherence rates was converted

from raw scores into a percentage to allow comparison across studies.

Results

Of 2613 articles originally identified through the application of search terms, 69 references were finally included for analysis. [Figure 1](#) illustrates the PRISMA-ScR flow chart constructed.²⁴ An overview of included studies is presented in [Appendix 2](#). The initial search using the MESH terms venous leg ulcers AND chronic venous insufficiency, was too narrow and excluded many relevant articles. When included as an “OR” MESH term, a nonsensical number of articles was identified hence the need to manually assess each article based on the parameters of this review. Following an initial screening of title and abstract, the original number was reduced to 282. Two separate phases of snowballing followed, manually screening reference lists from full-text articles, yielding a further 54 articles. Forty-eight duplicates were removed after the first phase of snowballing and a further 107 articles that did not meet inclusion criteria were removed after the second phase. Finally, 126 full text articles were printed and assessed for eligibility with a total of 57 excluded (reasons provided in [Figure 1](#)). This left 69 articles that fulfilled the eligibility criteria.

Bibliographic Analysis

Publications by Year

There has been a steady increase in publications since 1991 ([Figure 2](#)). From 2011 to October 2019, 38 articles that met inclusion criteria have been published. No papers prior to 1991 were identified.

Publications by Research Method

The 69 included papers were grouped using the Levels of Evidence Pyramid²⁹ ([Figure 3](#)). Four systematic reviews, three critically appraised topics, 14 randomized controlled trials, 17 prospective cohort designs, five retrospective cohort designs, nine case studies/reports, 13 background papers and four interview-based qualitative designs were identified.

Developing a Conceptual Framework

The themes emerging logically through scoping the multidisciplinary bodies of knowledge are visually represented in a conceptual framework ([Figure 4](#)). These themes are presented below, aligned to research questions 1–3. Research question 4 (knowledge gaps) is presented throughout.

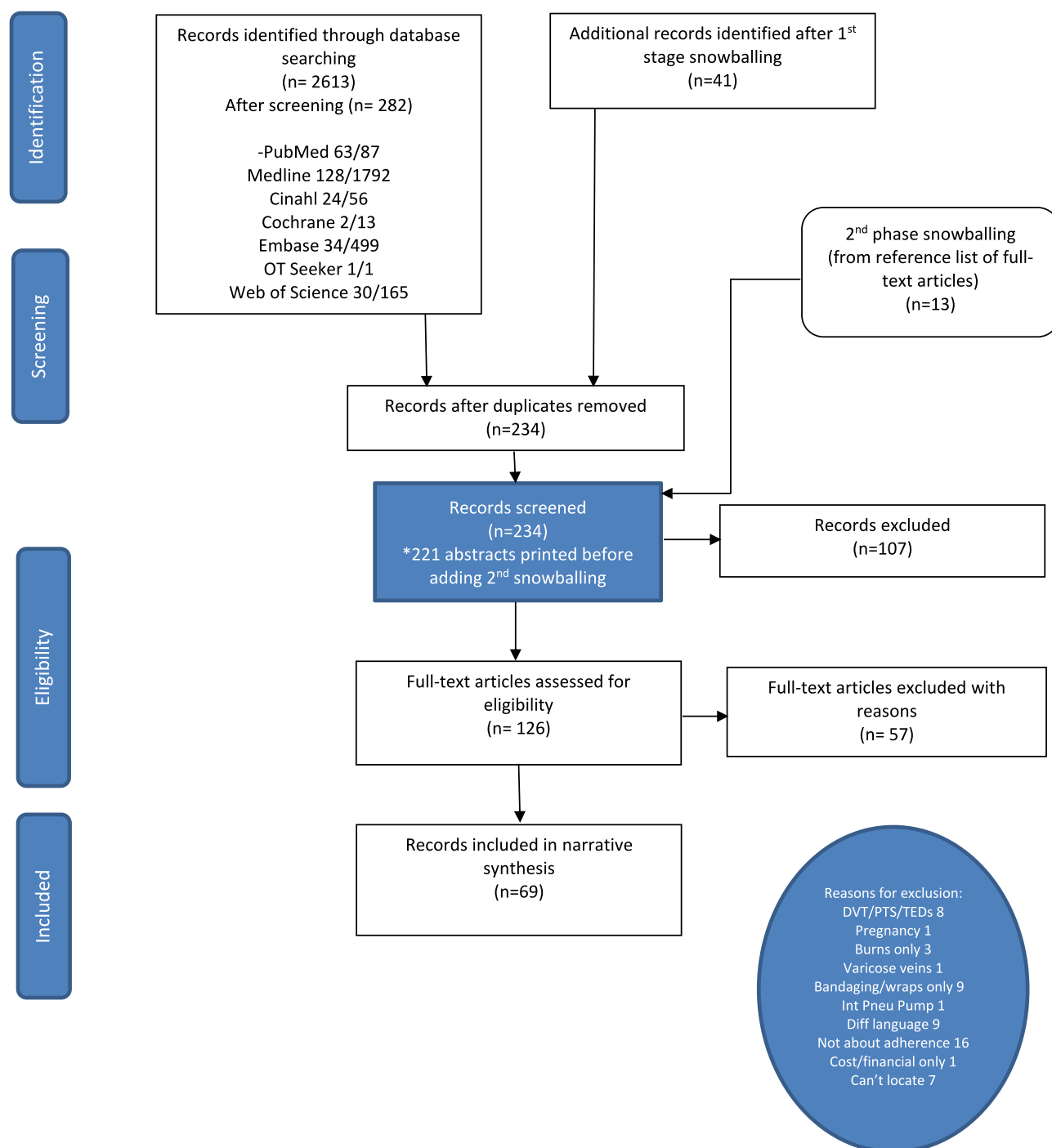


Figure 1 Study flow diagram (PRISMA-ScR flow chart²⁴). Adapted from Tricco AC, Lillie E, Zarin W et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Ann Intern Med.* 2018;169(7):467–473.

Modifiable Variables That Improve Adherence

Question one: What factors and interventions have been reported in the literature to attempt to improve compression stocking adherence?

A variety of interventions have been investigated but reported outcomes on adherence have not shown consistent or definitive preference for any intervention.

Consequently, the evidence does not currently support any intervention over others. Factors reported to improve patient adherence fell within three main themes: a) The way that health care professionals (HCPs) interact with patients, b) educational delivery designs, and c) variations in application and removal of stockings. Most studies with larger cohorts attempted to improve stocking adherence

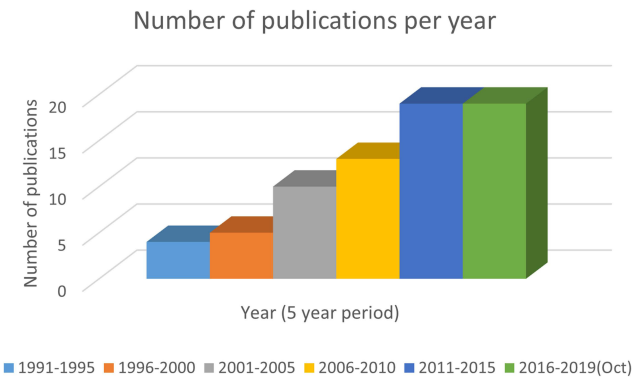


Figure 2 Number of publications by year from inception to conclusion of the search.

through unidimensional approaches but reported limited impact. Conversely, some smaller studies (N=1–4) have generally reported positive impacts on adherence with personalized, multidimensional approaches. [Table 1](#) summarizes the outcomes from interventions on adherence.

a) Fourteen articles^{6,21,30–41} discussed how HCPs can influence adherence. Predominantly discussion articles (N=12), only two (case studies)^{30,32} attempted to directly influence adherence. A review³⁸ investigated stocking adherence after VLU healing, recommending that HCPs should ensure that their communication enhances the perceived value of compression stockings to improve

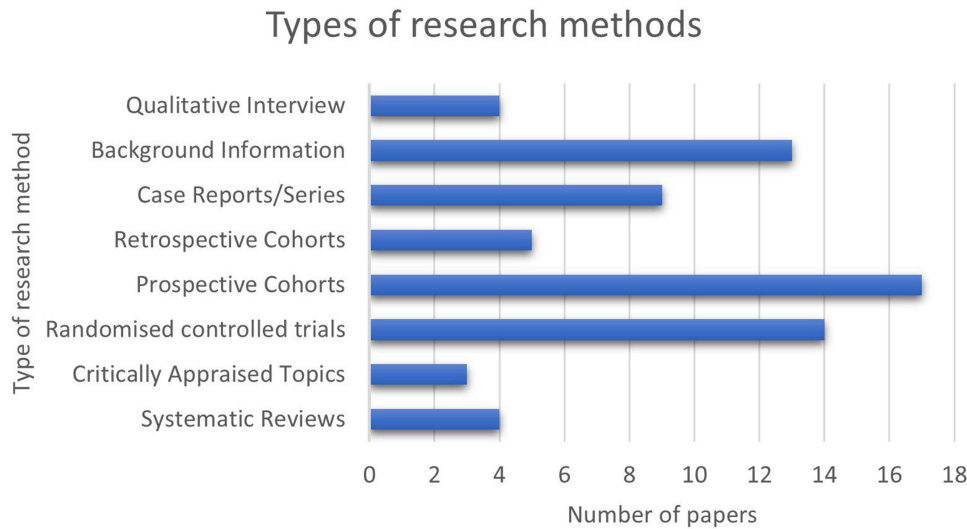


Figure 3 Publication count organized by level of evidence.

Conceptual Framework: Adherence

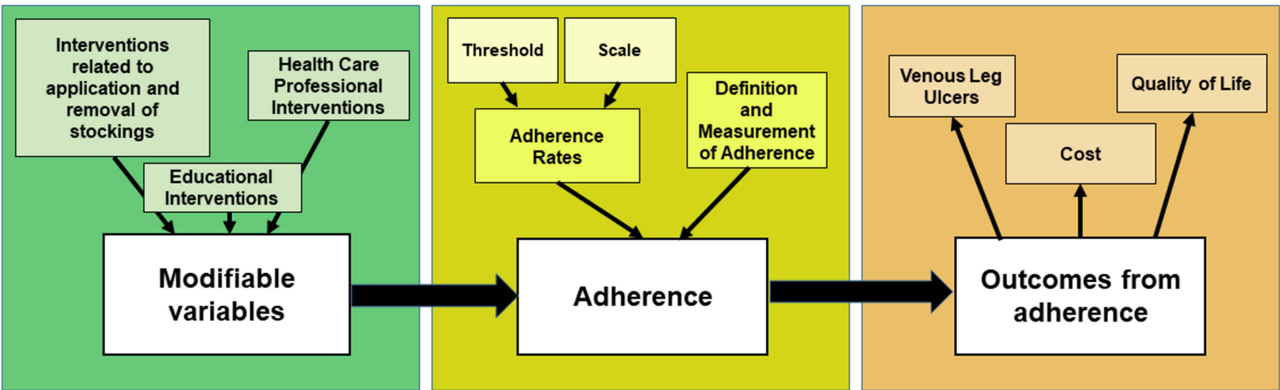


Figure 4 Conceptual Framework of Adherence.

Table I Impact of Interventions on Adherence

Study	Type	Variable(s) Modified		Adherence
		Main	Second	
Benigni, J.P., et al ⁵⁰	RCT	Stocking gradient (degressive versus progressive)	Nil	No measurable adherence outcome provided
Brooks, J., et al ⁶⁰	RCT	Education program versus usual care	Nil	No significant difference between groups
Christensen, C.R. and Yaeger, A.A. ⁶⁵	Case study	Patient contract (collaboration)	Bed alarm	Improved adherence for the case studied
Clarke-Moloney, M., et al ⁵¹	RCT	Class 1 versus class 2	Nil	Both groups improved equally
Dickey, J.W. ⁶⁶	Case series	Unna's paste + elastic compression + pump	Education	Improved adherence for the cases studied
Franks, P.J., et al ⁵²	RCT	Stocking brand 1 versus brand 2	Nil	No significant difference between groups
Ham, S. and Padmore, J. ⁴⁶	Case series	Compression hosiery kits	Nurse training	Improved adherence for the cases studied
Hampton, S. ⁴⁷	Case study	Ready-wrap stockings	Carer training	Improved adherence for the case studied
Heal, D. ⁶⁷	Case series	Soft-fit addition	Nil	Improved adherence for the cases studied
Heinen, M., et al ⁶¹	RCT	Education program versus usual care	Nil	No significant difference between groups
Kapp, S., et al ⁵⁸	RCT	Class 2 versus class 3	Nil	Adherence higher in class 2
Krijnan, R.M.A., et al ⁶²	RCT	Rubber mat versus stocking	Nil	No significant difference between groups
Lindsay, E and Hawkins, J. ³⁰	Case study	Collaboration with patient	Various compression styles	Improved adherence for the case studied
Lurie, F. and Schwatz, M. ⁶³	RCT	Pump versus stocking	Nil	No significant difference between groups
Milic, D.J., et al ⁴⁵	RCT	Class 2 versus class 3	Nil	Adherence higher in class 2 (not statistically significant)
Milic, D.J., et al ⁶⁴	RCT	Class 3 stocking versus bandaging A versus bandaging B	Nil	Adherence higher in class 3 (no significance data provided)
Mullins, M., et al ⁴⁸	Case series	Extremity Ease (stocking with zipper)	Collaboration	Improved adherence for the cases studied
Murdoch, V ³²	Case study	Prescribing pyramid (collaboration)	Various compression styles	Improved adherence for the case studied
Nelson, E.A., et al ⁵⁷	RCT	Class 2 versus class 3	Nil	Adherence higher in class 2
Protz, K., et al ⁴³	RCT	Education program versus usual care	Nil	Adherence higher in education group (no significance data provided)
Rees, R. ⁴⁹	Case study	High class to low class	Carer training	Improved adherence for the case studied
Uhl, J., et al ⁴²	RCT	Education program versus usual care	Nil	Adherence higher in the education group
Zajkowski, P.J., et al ⁵³	RCT	4 stocking brands	Nil	No significant difference between groups

adherence. A case study³⁰ described how one patient's healing rate improved when she was given more control over her own care, through a partnership formed with her nursing team. Another study³² highlighted the contribution of encouraging patient health ownership, which promoted autonomy, adherence and a better outcome. The development of a partnership between the HCP and the patient was specifically recommended in four articles.^{30,38,40,41} This is a situation where care plans are negotiated, and the HCP considers the patients' knowledge, experiences, beliefs, and practical needs. Emotive terms like empathy,³³ honesty³⁴ and mutual respect³² are mentioned, with several papers^{21,34,36} advocating that patient-centered care is the gold standard to be achieved. The concept of developing a non-judgmental relationship, where no "blame" is placed on the patient, is also endorsed.^{6,18,31}

b) In the theme of education, four studies^{41–43,60} used various modalities aiming to improve adherence. A quasi-RCT⁴³ showed benefit from using a brochure to improve patient knowledge, reporting that this led to higher adherence. A prospective cohort study⁶⁰ reported that there was a different outcome depending on the source of the information provided. This study reported that adherence was greater amongst patients attended by vascular specialists (93% adherence) as opposed to general practitioners (67% adherence). An RCT⁴² concluded that repeated HCP recommendations followed by mobile phone text reminders increased adherence from 33% to 48% in the control group and to 71% in the intervention group. A nurse-led prospective cohort intervention⁴¹ used education as a primary tool to improve conservative management of VLU, reporting that the education provided positively influenced participants' adherence to lifestyle advice generally but did not increase the amount of time that compression stockings were worn.

c) Fourteen articles^{45–58} reported on the participant's ability to manage the task of application or removal of stockings as an influential factor on adherence. Difficulty applying and removing compression stockings is a known barrier to adherence.⁵⁴ Clinically it is acknowledged that some stockings are easier to apply than others (for example lighter compression).^{57,58} Also, certain physical attributes increase the ease of application, (for example lower body mass index).⁵⁵ Twelve studies reported on interventions to attempt to improve adherence by varying specific properties of the stockings themselves. Three studies^{49,51,56} compared light (class 1) to moderate (class 2) compression. The case study by Rees⁴⁹

documented that the lighter compression improved adherence while the remaining two studies did not report statistically significant results. (Suehiro⁵⁶ did not disclose results. Clarke-Moloney⁵¹ reported $P=0.760$). Three further studies^{45,57,58} compared moderate (class 2) to high (class 3) compression and supported the widely held assumption that higher compression is less tolerated and more difficult to apply, though Milic's study⁴⁵ did not report statistical significance $P=0.188$. Nelson⁵⁷ recommended that patients should wear the highest level of compression that is comfortable for them. Two studies^{52,53} comparing brands of stockings demonstrated no difference in adherence rates and neither was easier to apply than the other. A RCT⁵⁰ comparing a degressive (tighter at the calf and looser at the ankle) stocking to a progressive (standard graduation – tighter at the ankle and looser at the calf) found that the degressive stocking was easier to apply but did not significantly improve adherence. Other papers^{46–48} discussed alternative methods of applying compression stockings, for example an altered stocking design or adjustable compression wraps, with recommendations that these may assist to improve adherence in some patients who have difficulty with standard graduated compression stockings. The remaining papers included a qualitative analysis using structured interviews⁵⁵ and a literature review where the author⁵⁴ recommended that all patients should be educated on the application of compression stockings and have application devices made available to them if needed.

Real-world studies such as case studies, may provide evidence on the effectiveness of an intervention in clinical practice,⁵⁹ even though RCTs are considered gold standard for evaluating the efficacy of an intervention. Brought together, these different study types can add more depth to an understanding of an intervention.⁵⁹ Further analysis of the 69 articles identified 23 studies attempting to directly influence adherence through modifying one or more variables, including 14 RCTs^{42,43,45,50–53,57,58,60–64} and nine case studies (or case series).^{30,32,46–49,65–67} These were categorized by study design, and by the number and type of variables that were modified. The variables investigated are represented in Figure 5.

All RCTs modified a single variable within their study design, that is, they were unidimensional. Five of the 14 RCTs described an increase in adherence after the intervention. One⁴² was related to the variable of education, while three^{45,57,58} provided evidence that lowering compression strength may improve adherence but then increase risk of VLU recurrence. In a study⁶⁴ comparing compression levels

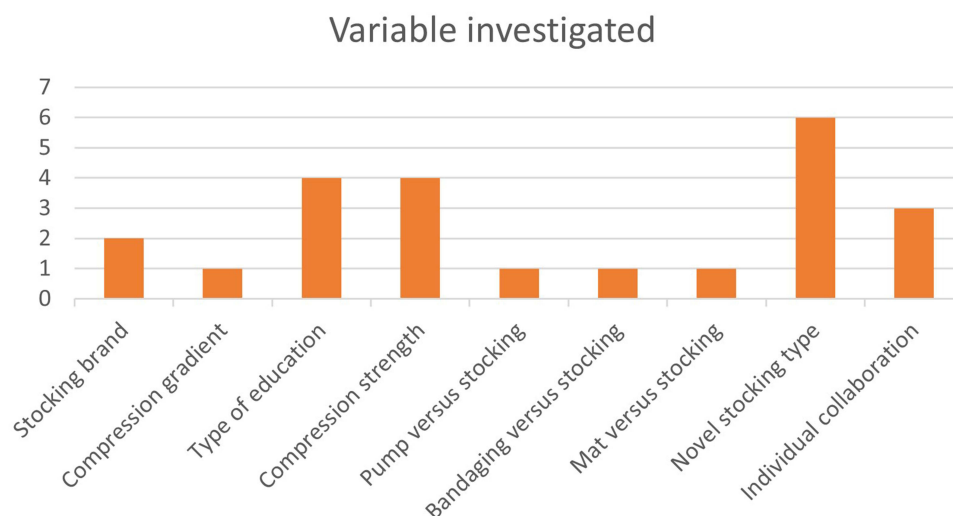


Figure 5 Variables investigated in the RCTs and case studies/series.

on adherence, the Class 3 group showed improved adherence compared to two types of bandaging, though no significance data was provided. Nine case studies/series described successful attempts to influence adherence. Six of these studies^{46–49,66,67} used personalized novel approaches to garment prescription (Velcro wraps, grip tops, zippers and compression kits) while three^{30,32,65} advocated for a personalized collaborative approach, involving health professionals and significant others in patient care. Eight of the nine case studies/series^{30,32,46–49,65,66} reported on a personalized multidimensional intervention, modifying at least two variables in the treatment plan.

Adherence

Question two: How has adherence been defined in the literature and how have adherence rates been reported and measured in the population of VLU and CVI?

Included studies present variable, and at times, conflicting descriptions of adherence, which are subject to interrelated concepts of the definition, measurement, and rate. Fourteen studies^{9,38,41,42,44,61,63,68–74} considered adherence a primary outcome measure where the remainder discussed adherence as a secondary outcome measure or as a point of discussion. Thirty studies reported a numerical adherence rate as an outcome of a study. Eight of the studies^{7,9,42,60,68,72,75,76} providing adherence rates did not give a clear definition of adherence. Studies defined adherence through various domains (adherence or a broader grouping with other factors) by measurement scale (dichotomous or interval) and/or with a stated

threshold. Table 2 collates a meaningful sample of this information.

- Definitions of adherence: There is great variability in how adherence is defined. Only 28 of the 69 studies provided a description of their determination of adherence, and three of these^{31,56,58} did not describe how they measured it.
- Domains: Most studies reported exclusively on adherence in terms of compression wear alone, while some had a broader definition which included, for example, attendance at appointments, wound care, exercise, and leg elevation.^{41,60,61}
- Scales: Of those who provided an adherence rate (N=30), most (N=18)^{12,16,44,45,56–58,60,62,63,68,73,74,77–81} documented whether their participants were adherent or not adherent as a dichotomous score. That is, participants either followed the prescribed wearing protocol or not. Eleven studies described an interval scale^{9,38,42,51,52,61,69,71,72,82,83} ranging from three to eight ranks, but only two^{38,51} of these explained which of their ranks were then classed as adherent or non-adherent. For example, Ayala⁶⁹ utilized a 4-ranked interval scale to categorize stocking wear however did not describe which ranks was classed as adherent versus non-adherent.
- Thresholds: The variation in behavioral criteria for an adherent or non-adherent classification was considered. One hundred percent adherence was required in a study⁸¹ assessing adherence

Table 2 Adherence: Measurement, Scale, Requirement for Achieving Adherence, and Rate

Process	Measurement Scale					
	Dichotomous			Interval		
	Study	Requirement for Achieving Adherence	Rate %	Study	Requirement for Achieving Adherence	Rate %
Self-reported questionnaire	Al Shammeri O, et al ⁷⁹	Collected the CS from the store, used it regularly and noticed an effect (good, not comfortable, or neutral) and would recommend it	50	Clarke-Moloney M, et al ⁵¹	All day every day - removing at night; some part of each day; some days, all day, and all night; or not at all^ <i>Dichotomy: All day every day – removing at night versus the other alternatives</i>	88.9
	Cataldo J. L, et al ¹⁶	Daily use exceeding 6 hours	59.4			
	Finlayson K, et al ²	Daily use of CS	47			
	Shannon M.M, et al ⁷³	Wearing every day	73			
	Ziaja D, et al ⁷⁴	Wore stockings daily (not occasionally)	27, 20			
Self-reported Journal	Benigni J.P, et al ⁸⁰	Worn for the minimum period (ie 6 hours), equal or greater than 80% of the time	95			
Self-report Interview	Krijnen R. M.A, et al ⁶²	Wore CS almost every day at work	66.6	Ayala A, et al ⁶⁹	Not wearing at all/never; used intermittently (up to 50% of the time), most days (50–100%) and, as prescribed^*	31.8
				Franks PJ, et al ⁵²	All day every day; some of the day or some days; some of the time^*	84 +81
				Heinen M, et al ⁶¹	Always, all day; occasionally somewhat shorter <2 hours <1 x per week; regularly somewhat shorter <2 hours shorter >1 x per week; occasionally, considerably shorter, >2 hours per week; regularly, considerably shorter >2 hours per week, > once per week; occasionally not, for one day, less than once per month; not, on a regular basis, more than once per month; not, in the last 6 months, more than one day at a time^*	45
				Heinen M, et al ⁷⁰	8 scales reduced to 3: Fully; moderately (2 hours less than all day); non-adherent^*	39
				Jull A. B, et al ³⁸	Wore stockings every day; most days; occasionally; never^ <i>Dichotomy: Every day and most days versus occasionally or never</i>	52

(Continued)

Table 2 (Continued).

Process	Measurement Scale					
	Dichotomous			Interval		
	Study	Requirement for Achieving Adherence	Rate %	Study	Requirement for Achieving Adherence	Rate %
Professional Recorded	Brooks J, et al ⁶⁰	Wore compression every day	55–66	Raju S, et al ⁷²	Daily wear (regular use); less consistent (most days); infrequent use (sometimes or seasonally); not at all ^{Λ*}	21
	Erickson C.A, et al ⁸¹	Kept 100% of their appointments, adhered completely with prescribed CS, and followed all instructions for wound and extremity care	32.3	Samson R.H et al ⁹	Good (well-fitting worn daily and new CSs bought as necessary); poor (if loose or worn-out CSs were used or were worn irregularly); and none (CSs were not worn at all) ^{Λ*}	47
	Mayberry J.C, et al ⁷⁸	Wore stockings all day, removed at night	79			
	Milic D. J, et al ⁴⁵	Wore CS 80% of the time during the 1st and 2nd years and >50% of the time during 3rd, 4th and 5th years	89 and 93			
	Stansal A, et al ⁴⁴	Wore CS to the appointment, correctly applied, and effective	89			
Combination	Allaert F, et al ⁶⁸	>3 on Adhesig (Self-report via questionnaire + Thermosensors)	74	Bogachev V, et al ⁸²	As prescribed, most days, intermittently or not at all ^{Λ*}	29.1
	Hanley T.P, et al ⁷⁷	Wore CS on a regular basis (4–7 days) each week (Observation and self-report)	37	Manduz S, et al ⁷¹	CSs: suggested but did not buy; recommended, bought but not used enough; recommended, bought, and used for a short time; recommended, bought, and used irregularly; recommended, bought, and still uses ^{Λ*}	Unclear
	Lurie F, et al ⁶³	Wore stockings during all wakeful hours for 30 days. At least 10 hours per day (Device meter and self-report via diary)	85			
	Nelson E. A, et al ⁵⁷	Wore the allocated class of CS throughout the study (Self-report and observation)	58 and 72			
	Uhl J, et al ⁴²	Average number of days worn (not a definition per se)	48 and 71			
	Van Hecke A, et al ⁴¹	Wore every day except 2–3 days per month, wore 5–6 days per week, > 10 hours per day (Self-report via diary and interview)	Not provided			

(Continued)

Table 2 (Continued).

Process	Measurement Scale					
	Dichotomous			Interval		
	Study	Requirement for Achieving Adherence	Rate %	Study	Requirement for Achieving Adherence	Rate %
Not described	Arpaia G, et al ⁷⁶	Description not provided	91.6			
	Kapp S, et al ⁵⁸	Wore CS for >50% or nonadherent <50%	44.1			
	Motykie G.D, et al ⁷⁵	Description not provided	82			
	Suehiro K, et al ⁵⁶	CS worn > 5 days per week	80			

Notes: ^Interval scale converted to dichotomized scale by study authors. *No explanation provided for conversion to dichotomous score.

Abbreviation: CS, compression stockings.

related to physician instruction, while other studies^{12,51} had broad categories with poorly defined threshold scores, for example a study that considered purchasing the stocking an assumption of adherence.⁷¹ It is assumed that the stricter the parameters to define adherence, the lower the reported adherence rate. For example, in Hanley's study,⁷⁷ participants were classified as adherent if wearing their stockings 4–7 days per week. Similarly, Kapp's⁵⁸ RCT classified adherence as wearing stockings more than 50% of study days. However, Franks⁵² study investigating VLU recurrence rates in patients wearing either of two different brands of stockings considered a participant adherent if they "wore their stockings all day every day",⁵² demonstrating a much more arduous wearing regime required for their study participants to be classified as "adherent".

- (e) Measurement: Eight studies^{9,30,44,45,60,72,78,81} relied purely on observation by a clinician (nurses or physicians), while 15 studies^{12,16,38,41,51,52,61,62,69,70,73,74,79,80,82} relied on patient self-report delivered either verbally or via questionnaire or journal. Three studies^{57,71,77} used a combination of observation and self-report. A thermal-tracking device plus patient self-report was used in three studies.^{42,63,68} Six studies did not disclose how their information was recorded or collected.^{7,56,58,64,75,76}

Rates of adherence varied from 20.3 to 95%. Due to the variability in definitions and measurement, reported adherence rates (reported in Table 2) have limited reliability.

Outcomes from Adherence

Question 3: What is the impact of adherence on patient outcomes?

Variable levels of adherence to medically prescribed compression stockings can influence a person's physical, social, and psychological situation in various ways.⁵⁸ Outcome findings were separated into three key themes that appeared frequently in the literature, linking adherence to 1) VLU healing time/ recurrence 2) patient quality of life and 3) costs.

Studies that considered the link between adherence to stocking wear and VLU healing and recurrence were included and summarized in Table 3. Fifteen met these criteria, eight of which were RCTs,^{45,51,52,57,58,60,61,64} one was a systematic review,⁸⁴ one⁸⁵ provided background information, another was a case series report⁶⁶ and the remaining four were observational studies.^{9,77,78,81} All reported that low adherence with stocking wear is associated with delayed healing and increased recurrence of VLUs. Hanley⁷⁷ reported that 25% of those who were adherent at 2 years of follow-up developed adverse sequential sequelae compared to 53% of those who were non-adherent. In Mayberry's study⁷⁸ VLU healing occurred in 97% of those who were adherent versus 55%

Table 3 Adherence and Reference to Healing Time and Recurrence

Study	Variables Modified	Study Type	Outcome on VLU Healing/Recurrence
Brooks J, et al ⁶⁰	Usual care or education program	Quasi-experimental RCT	There was 4% VLU recurrence in intervention group and 36% in control (p=0.004). Outcome not related to adherence but to ankle movement, mobility level and leg elevation [#]
Clarke-Moloney M, et al ⁵¹	Class 1 or class 2	Pilot RCT	The lowest VLU recurrence rates were seen in patients who were adherent with CSs regardless of the compression level. 12-month recurrence rate recorded 16.3%. All patients wearing class 1 stockings developed a new ulcer [#]
Dahm K.T, et al ⁸⁴	N/a	Systematic review	Class 2 seems to be more effective in prevention of ulcer recurrence than class 1 [#]
Dickey J.W ⁶⁶	Pre and post intervention (CS and education)	Case series	An examination of the clinical course of each patient shows that the faster healing was causally related to compliance [#]
Erickson C.A, et al ⁸¹	Pre and post Unna's boot +class 3 CS	Retrospective cohort	Adherence reduced healing time and prolonged time to recurrence. At 5 months, VLU healing was 73% if adherent, and 59% if non-adherent [#]
Franks PJ, et al ⁵²	Brand 1 or brand 2	RCT	Recurrence rate was 26% after 1 year and 31% at 18 months for both brands [#]
Hanley T.P, et al ⁷⁷	Adherent or non-adherent patient	Prospective cohort	At 2 years the adherent group had no skin changes; 28% of non-adherent group had skin changes including VLU in some. At 60 months none of the adherent group had ulceration but 8.6% had stasis changes. Of non-adherent patients, 63% had chronic skin changes [#]
Heinen M, et al ⁶¹	Usual care or lifestyle counselling	RCT	The intervention group had fewer wound days (p<0.01), but time to recurrence did not differ significantly (p=0.07) ^{<}
Kapp S, et al ⁵⁸	Moderate CS or high CS	RCT	Study wound recurrence was 11.8% within 26 weeks, and average time to recurrence was 77.91 days. Adherence to treatment significantly predicted study wound recurrence (p=0.005). Those who did not adhere to CS were 9x more likely for the wound to recur. Recurrence risk was 3 x greater for moderate compared to high compression [#]
Mayberry J.C, et al ⁷⁸	Pre and post CS	Prospective cohort	Of 113 patients, 102 were compliant with CS: 11 were not. Only non-compliance with CS (p<0.0001) and a pre-treatment VLU duration of more than 9 months (p<0.02) significantly decreased initial VLU healing. All noncompliant patients had recurrent ulceration by 36 months [#]
Milic D.J, et al ⁴⁵	Class 2 or class 3	RCT	Class 3 had lower VLU recurrence rate compared to class 2: 28.98% versus 60% (P<0.001) [#]
Milic D.J, et al ⁶⁴	Class 3 CS or 2 types of bandages	RCT	The healing rate for VLU area of 5–10cm ² in group A (Class 3 CS) was 25%, 64% in group B (bandages) and 75% in group C (another type of bandages) [#]
Moffat C, et al ⁸⁵	N/a	Critically appraised	6 studies indicate that the healing rate was half and the median time to complete healing was twice as long when Pts were not concordant. Recurrence rates were 2–20 times greater if not concordant post healing [#]
Nelson E.A, et al ⁵⁷	Class 2 or class 3	RCT	36% had recurrent VLU by 5 years. 39% of these did not comply with their randomized compression class in class 3, and 28% in class 2. No statistical difference between classes on VLU recurrence, though fewer patients had ulcers in class 3 [#]
Samson R.H et al ⁹	Pre and post CS	Prospective cohort	Of the 25 pts who were compliant only one developed a recurrence. Of the 28 who were 'poor' or 'none', 22 developed at least one recurrence ^{<}

Notes: [<]Adherence is the primary outcome measure. [#]VLU is the primary outcome measure.

Abbreviations: VLU, venous leg ulcer; CS, compression stockings.

who were non-adherent, where all patients who were non-adherent had recurrent ulceration by 36 months. Moffat's 2009 review⁸⁵ identified that six of the ten studies included, reported that the medium time to complete healing was twice as long when patients were non-adherent. Furthermore, recurrence rates were 2–20 times greater if non-adherent post-healing. The evidence clearly suggests that adherence with compression therapy is vital in healing and prevention of VLUs and that the tighter the compression, the better.^{45,51,84}

Seven papers^{6,41,42,55,63,75,80} discussed patient quality of life (QoL) as a clinical outcome measure of wearing compression stockings, however only three of these^{42,63,75} used validated assessment tools, and the link between adherence and QoL was not well explored. A single paper reported that patients perceived compression to be "inconvenient and doubtful in improving quality of life".⁵⁵ However, this was an exception, as other included studies testified positively on QoL. Motykie⁷⁵ reported that patients became less depressed about the appearance of their legs, began to sleep more routinely, and began to increase daily activity levels when they had commenced compression stocking wear. Using a thermal sensor to verify patient self-report, Uhl⁴² found that there is significant correlation between wearing time, and two parameters of a QoL questionnaire: psychic and social (both $P < 0.001$), however no correlation was found with physical or pain parameters. Only four of the included papers commented meaningfully on cost.^{7,9,16,32} Murdoch³² reported that prevention of VLUs is generally more cost-effective than management of the resulting disorder.

Discussion

This is the first scoping review to report on the breadth of literature relating to adherence with compression stockings in the VLU and CVI population. Themes emerging from the literature and presented in a conceptual framework (Figure 4), revealed several key findings.

Firstly, with respect to variables that improved adherence, larger studies investigating unidimensional approaches reported little success. In contrast smaller, albeit less robust investigations of multidimensional approaches, hint at greater impact on improving adherence. As most patients with low adherence often have multiple barriers to wearing compression stockings,⁸⁶ studies that modify only a single variable may not influence a proportion of study participants for whom that single variable is not relevant. It is also possible that multiple

factors influence adherence and therefore interventions targeting a single variable may be destined to fail. This sentiment is echoed in recommendations for the management of other chronic diseases including diabetes mellitus⁸⁷ and chronic kidney disease⁸⁸ through acknowledgement of the complexities of individuals and their environments. The literature investigating unidimensional approaches lacks relevance for clinicians who gather information in multiple fields within their assessment. Van Hecke's 2009 literature review¹⁸ provided early support, recommending that future attempts to address the complex issue of low stocking adherence, should aim to consider comprehensive multidimensional packages, personalized to an individual's needs. Furthermore, neither unidimensional nor multidimensional studies that have attempted to improve adherence have been able to show a definitive preference for any intervention over others. Clinicians need greater evidence-based clarity regarding approaches to improve adherence with compression stockings and therefore further robust research into multidimensional patient centered approaches is needed.

Secondly, the lack of consistent definitions of adherence and measurement parameters underpins the wide range in reported adherence rates in the literature and simultaneously creates an impediment to clinical practice and research. For example, lower rates of adherence will be reported when stricter parameters must be complied with to meet the criteria for adherence and the converse relationship will also exist. Moffat's⁸⁵ 2009 literature review reached a similar conclusion, attributing wide variability in reported adherence rates to contextual differences amongst trials. Dichotomous reporting of adherence may reduce the sensitivity of its measurement, yet the interval scales used to date, lack justification or explanation of their thresholds for defining adherence. Patient self-report is the predominant method of measuring adherence, despite existing concerns around the validity of this method due to risk of memory bias and vulnerability to social desirability.⁸⁹ A superior method of ThermoTrackers does exist, but cannot be used in all climates,^{42,68} and their use could present an unacceptable cost to researchers. Van Hecke's 2009 literature review of studies reporting on reasons for low stocking adherence agreed with the findings from this review, where studies showed poor consistency in defining and operationalizing adherence.¹¹ Lack of clarity and consistency in defining adherent behavior may undermine the reliability and validity of research findings.

Finally, investigating the outcomes from adherence revealed that improved adherence correlates with improved health outcomes, which is consistent with prior authors.^{41,42} Despite the importance of cost, out of 69 included studies, only four in this review reported on this relationship. Some authors^{4,14} have reported a link between improving stocking adherence and reduced health costs but there remains a sparsity of health economic evidence regarding this link. Evidence suggests that there may be an improvement in quality of life for those who adhere with compression stockings because of a negative association between VLU and QoL,⁹⁰ and because healing rates improve and recurrence decreases with better adherence,^{9,58,77} but studies in this review have included very limited information about this. Consequently, greater intelligence regarding the quality of life and economic impacts of improving adherence, are required from future research to better inform policy and funding in this area.

Several key gaps in the literature were identified. The lack of agreement in defining adherence with compression stockings, and the inconsistency in methods of measuring adherence is clearly evident from this review. The variations in behavioral criteria for an adherent or non-adherent determination between studies, restricts our confidence in making comparisons. The literature also reveals limited success in improving adherence to compression stocking wear in populations where each participant has unique and often multiple barriers to compression therapy. Personalized, multidimensional approaches to treatment have shown promise in small studies but have not been implemented in large populations. Health economic outcomes have not been adequately explored relating to different levels of adherence. Nor has the connection between quality of life and adherence been clarified.

Directions for Future Research

A consistent definition and scoring system for adherence would allow improved comparison between studies such as the standardized tools used to measure medication adherence.⁹¹ A more sensitive tool with an interval scale is needed. Personalized multidimensional approaches may be more likely to improve adherence. Future attempts to address this complex issue should aim to consider multidimensional packages, personalized to an individual's needs. Considerations include education, negotiation, and stocking selection tailored to patients' tolerance for compression and their ability to apply and remove stockings. Further, a high-quality trial to investigate the cost-

effectiveness of such an intervention is recommended to improve our understanding of the financial implications and to consider any perceived patient and societal benefit.

Strengths and Limitations of This Review

A strength of this review is its breadth and overview of the topic, also the new synthesis of information to aid understanding of adherence with compression within this patient group.

This review also had some limitations. Firstly, some factors with potential to impact adherence were excluded on the basis that they are non-modifiable at the time of intervention, such as climate, cognitive ability, and religious beliefs. This was an intentional decision, to focus the review results and conclusions on modifiable factors more able to be targeted with subsequent clinical research. Finally, the search was limited to the English language as language translation was beyond the scope of this work. A further three studies^{92,93,94} that met inclusion criteria appear in Appendix 2 but are not cited in other tables or key themes within this review.

Conclusion

The often opaque and inconsistent way in which adherence with compression stockings has been measured and defined, currently limits meaningful comparison between studies, reducing the potential impact of clinical trials attempting to improve adherence. A variety of interventions have been investigated, but none have shown clear or consistent superiority over others. RCTs have generally investigated unidimensional interventions, which have been greatly unsuccessful in improving adherence. Multidimensional interventions have demonstrated more positive impacts on adherence but to date have only been investigated in smaller cohorts, case series or case studies. Improving adherence appears to improve health outcomes for patients with VLU/CVI but there is a lack of information directly linking improved adherence with cost outcomes. Consequently, the present evidence-base provides little support for clinicians seeking to improve patient adherence with compression. There is a need for high-quality trials of multidimensional interventions targeting adherence with clear definitions and simultaneous cost evaluation.

Abbreviations

CEAP, system of classification of chronic venous disorders; CS, compression stocking; CVI, chronic venous

insufficiency; HCP, health care professional; N, number; OTS, off the shelf; QoL, quality of life; RCT, randomized controlled trial; V, versus; VAS, visual analogue scale; VCSS, venous clinical severity score; VLU, venous leg ulcer.

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