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# BMJ Open

## ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL

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Manuscripts

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3 **ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC**  
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5 **LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL**  
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# ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL

## ABSTRACT

**Objective:** This review aims to determine the effectiveness of the treatment of wound healing in venous leg ulcers by assessing the quality of the evidence available.

**Methods:** A literature search in PubMed, CINAHL, Scopus, Web of Science, Cochrane Library, BVS/BIREME, Embase, ProQuest, BDTD, Thesis and Dissertation Catalog, Sao Paulo Research Foundation Research Foundation/Thesis and dissertation, OPEN THESIS, A service of the U.S. National Institute of Health, Center for Reviews and Dissemination- University of New York and SciElo published in the last 10 years. To be included, studies need to be primary (original), and Controlled Trials or Observational studies (cross sectional, case-control or longitudinal studies). Exclusion will include leg ulceration due to different causes, such as pressure, arterial, diabetic or mixed an etiology leg ulcer.

**Results:** The primary outcome measures are the proportions of wounds with complete healing. Two reviewers will independently assess the quality of the included studies by using the standardized critical appraisal instruments from the Joanna Briggs Institute. Data synthesis will be performed using a narrative summary and quantitative analysis.

**Ethics and dissemination** This systematic review does not require ethical approval, as individual patient data will not be collected. Dissemination of findings will be through publications in peer-reviewed journal.

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3 **PROSPERO registration number CRD42019127947**  
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6 **Strengths and limitations of this study**  
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- 10 • To know the effectiveness of Unna boot dressing in the management of VLU will  
11 contribute to the use of a low-cost alternative to wound healing. VLUs has not been  
12 studied; our systematic review will be the first to answer the question.  
13
- 14 • The eligibility criteria used may not result in the selection of studies that are  
15 homogeneous in methods limiting the ability to draw reliable conclusions.  
16
- 17 • Limitation: Only article published in English, Spanish, and Portuguese will be considered.  
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26 **BACKGROUND**  
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28 Venous leg ulcers cause significant social and economic impact due to their recurrent nature and  
29 the long time elapsed between their opening and healing. VLU is a result of venous hypertension  
30 caused by chronic venous insufficiency. The consequences of venous insufficiency include  
31 edema, dermatitis, hyperpigmentation, skin fibrosis and subcutaneous tissue of the leg and,  
32 finally, ulceration (1–4).  
33

34 Compression therapy is the most important measure of the treatment of a person with VLU  
35 because it contributes to the venous return, improving stasis and edema, which translates into  
36 better clinical conditions in the lesion and helps shorting the healing time (4–6). Unna Boot is an  
37 inelastic compression therapy that acts to increase compression and promote drainage and venous  
38 support, improving healing of the ulcer (5).  
39

40 The compression during rest and muscle contraction, acts on the macrocirculation, increasing the  
41 venous return, and on the tissue pressure, supporting the reabsorption of the edema and the return  
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of the fluids located in the interstitial spaces to the interior of the vascular and lymphatic system.

This process promotes the healing of the lesion and prevents inflammation (7–9).

The Unna boot consists of a low compression gauze (18-24 mmHg); the composition varies between the handmade form, which requires previous thermal heating, and the industrial one, that is ready for use, contains 10% of oxide of zinc, gum acacia, glycerol, castor oil and deionized water (10,11). According to studies, the use of the Unna boot is effective in promoting the satisfaction related to minimum wound care, rapid development of granulation tissue, improvement in comfort and lower costs relative to other compressions that have the same objective(7,10,12,13).

This systematic review aims to critically evaluate the effectiveness of Unna Boot on the treatment of chronic leg ulcers in adults by assessing the quality of the evidence available. Specific question addressed by the review is: Is the use of Unna Boot effective in the treatment of chronic leg ulcers in adults?

## **METHODS**

This protocol has been registered with the PROSPERO (CRD42019127947) and will be reported following the Preferred Reporting Items for Systematic Review and meta-Analysis Protocols (PRISMA) (14,15). This review will be report following standardised critical appraisal instruments from Joanna Briggs Institute (16,17).

### **Patient and Public Involvement**

No patients or public were directly involved in the development of this systematic review protocol.

## **SEARCH STRATEGIES**

We will systematically and electronically conduct searches on the following databases: PubMed (1999- 2019), PubMed/PMC( 1999- 2019), Virtual Health Library (BVS / BIREME) (1999- 2019), The Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1999- 2019), Scopus (1999- 2019), Web of Science (1999-2019), MEDLINE (CAPES) (1999- 2019), Embase(1999- 2019), Cochrane Library (1999- 2019), ProQuest (1999- 2019), Brazilian Digital Library of Theses and Dissertations (BDTD) (1999- 2019), CAPES / Thesis and Dissertation Catalog (1999- 2019) Sao Paulo Research Foundation/ Thesis and dissertation (1999-2019), OPEN THESIS (1999- 2019), A service of the U.S. National Institutes of Health (Clinical Trial)(1999- 2019), Centre for Reviews and Dissemination - University of York(1999- 2019), Scientific Electronic Library (SciELO)(1999- 2019).

## **SELECTION CRITERIA**

All Unna Boot related human studies for treating venous leg ulcers will be included.

## **STUDY DESIGN**

To be included, studies need to be primary (original), Controlled Trials or Observational studies (cross sectional, case-control or longitudinal studies). These studies will be used to assessing the effectiveness of Unna Boot on the healing of venous leg ulcers. Eligible studies must be in Portuguese, Spanish or English language.

## **TYPE OF PARTICIPANTS**

The participants are all adults' patients with venous leg ulcers on any location and of size. We will accept study authors' diagnostic criteria for the wound aetiology. The intervention of interest is Unna boot. Exclusion will include leg ulceration due to different causes, such as pressure, arterial, diabetic or mixed aetiology leg ulcers.

## **INTERVENTION**



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2  
3 The intervention will include Unna boot treatment of venous leg ulcers. Information about the  
4 time of use, initial wound size, sociodemographic and clinical will be documented.  
5  
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## 7 **COMPARATOR**

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10 Studies comparing any other type of dressing, topical agent, placebo or standard treatment will be  
11 included in this review.  
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## 14 **OUTCOME MEASURES**

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16 The primary outcome measures are the proportions of wounds with complete healing. We will  
17 consider the proportion of ulcers healed during follow-up and frequency of complete healing  
18 during the study. The rate of adverse effects and events (e.g. the wound infection rate and signs  
19 and symptoms of clinical infection) will be documented. Additional outcome(s), such as Quality  
20 of life (measured using generic questionnaire or a disease-specific questionnaire). And Pain (e.g.  
21 at dressing change or over the course of treatment) will be only included in validated  
22 questionnaires or visual analogue scales. Change in ulcer size will be consider using data on the  
23 change (and percentage change) in ulcer size, with adjustment for baseline size (we will contact  
24 study authors to request adjusted means when not available).  
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## 37 **STUDY SELECTION AND DATA MANAGEMENT**

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39 Two review authors will independently assess the titles and abstracts of studies found during the  
40 searches for potential inclusion in this review. Disagreements will be discussed during consensus  
41 meetings with a third review author. Potential relevant studies will be examined in full by two  
42 review authors. The studies that meet the eligibility criteria will be included in the review.  
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49 Disagreements will be discussed at consensus meetings with a third review author.  
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## 51 **DATA EXTRACTION**

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53 For data extraction: extracted information will include the study setting, study characteristics  
54 (authors, year of publication, country of publication, study design), details of the intervention and  
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control, research design, inclusion and exclusion, outcomes, characteristics of the examined patient demographics (number of subjects, gender, mean age, comorbidities, number of wounds treated), wound characteristics (mean wound duration, mean wound size) losses to follow-up, sensitivity analysis performed, author conclusions and conflicts of interest. Data extraction will again be performed independently by two reviewers, and any discrepancies will be resolved through group discussion.

### **ASSESSMENT OF RISK OF BIAS OF INCLUDED STUDIES**

Two reviewers will independently assess the quality of the included studies by using the standardized critical appraisal instruments from the Joanna Briggs Institute (JBI) (16,17). The instruments require the following data: title, authors, year of publication, journal, methodology, method, data analysis employed, configuration, geographical and cultural context, participants, interventions, main results and conclusions of authors and reviewers. After extracting the data, a level of credibility will be assigned to each finding, and the results will be synthesized through groups of data from primary studies. Disagreements between reviewers over the quality checklist will be resolved through discussion.

### **DATA ANALYSIS AND SYNTHESIS**

Data synthesis will be performed using a narrative summary and quantitative analysis. A meta-analysis considering models of random-effects will be employed to compare among groups based on outcome variables, if studies included in the review disclose sufficient data.

### **DISCUSSION**

This review aims to determine the effectiveness of the treatment of wound healing in VLU. This assessment will be performed by evaluating the total proportion of completely closed wounds relative to that of the start of treatment. Although studies have shown good results with

granulation tissue formation and wound healing (10,18), the effectiveness is currently unclear. To our knowledge, this is the first systematic review to evaluate the effectiveness of the Unna boot on wound healing. The result of this review may help health professionals and educators in the indication of the use of inelastic compression for patients with VLU in reality where financial resources are scarce.

### **AUTHORS CONTRIBUTION**

This study was conceptualized by MHML, TP, FCIC, and MFG, PPA developed the search strategy. FA and MGBS completed the search and drafted the protocol. APD, ARSOK, MGBS and HCO critically appraised the protocol and also contributed to its development by revising subsequent versions. MHM; ARSOK and HCO will contribute equally to the data collection and analysis, as well as the interpretation of the review. All authors will revise critically the review and will read and approved the final manuscript.

### **ACKNOWLEDGEMENTS**

Not applicable.

### **FUNDING**

There is no funding received for this study.

### **COMPETING INTERESTS**

The authors declare that they have no competing interests.

### **ETHICS APPROVAL AND CONSENT TO PARTICIPATE**

Not applicable.

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# 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-Reporting 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.

		Page
	Reporting Item	Number
<b>Title</b>		
Identification	<a href="#">#1a</a> Identify the report as a protocol of a systematic review	01

- 1 Update [#1b](#) If the protocol is for an update of a previous systematic  
 2 review, identify as such  
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 6 none  
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- 8  
 9 **Registration**  
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 12 [#2](#) If registered, provide the name of the registry (such as  
 13 PROSPERO) and registration number **CRD42019127947**  
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- 17 **Authors**  
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 20 Contact [#3a](#) Provide name, institutional affiliation, e-mail address of all  
 21 protocol authors; provide physical mailing address of  
 22 corresponding author **title page**  
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- 28 Contribution [#3b](#) Describe contributions of protocol authors and identify the  
 29 guarantor of the review **09**  
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- 33 **Amendments**  
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 35  
 36 [#4](#) If the protocol represents an amendment of a previously  
 37 completed or published protocol, identify as such and list  
 38 changes; otherwise, state plan for documenting important  
 39 protocol amendments **none**  
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- 46 **Support**  
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 49 Sources [#5a](#) Indicate sources of financial or other support for the review  
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 51 **07**  
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- 55 Sponsor [#5b](#) Provide name for the review funder and / or sponsor **07**  
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1	Role of sponsor	<a href="#">#5c</a>	Describe roles of funder(s), sponsor(s), and / or institution(s),	
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3	or funder		if any, in developing the protocol	<b>07</b>
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5				
6	<b>Introduction</b>			
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10	Rationale	<a href="#">#6</a>	Describe the rationale for the review in the context of what is	
11			already known	<b>02</b>
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14				
15	Objectives	<a href="#">#7</a>	Provide an explicit statement of the question(s) the review	
16			will address with reference to participants, interventions,	
17			comparators, and outcomes (PICO)	<b>03</b>
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22	<b>Methods</b>			
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26	Eligibility criteria	<a href="#">#8</a>	Specify the study characteristics (such as PICO, study	
27			design, setting, time frame) and report characteristics (such	
28			as years considered, language, publication status) to be	
29			used as criteria for eligibility for the review	
30				<b>03-04</b>
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38	Information	<a href="#">#9</a>	Describe all intended information sources (such as electronic	
39			databases, contact with study authors, trial registers or other	
40	sources		grey literature sources) with planned dates of coverage	<b>03-</b>
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48	Search strategy	<a href="#">#10</a>	Present draft of search strategy to be used for at least one	
49			electronic database, including planned limits, such that it	
50			could be repeated	<b>03-04</b>
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1	Study records -	<a href="#">#11a</a>	Describe the mechanism(s) that will be used to manage	
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3	data		records and data throughout the review	04
4				
5	management			
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8	Study records -	<a href="#">#11b</a>	State the process that will be used for selecting studies	
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10	selection process		(such as two independent reviewers) through each phase of	
11				
12			the review (that is, screening, eligibility and inclusion in	
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14			meta-analysis)	04
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16	Study records -	<a href="#">#11c</a>	Describe planned method of extracting data from reports	
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18	data collection		(such as piloting forms, done independently, in duplicate),	
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20	process		any processes for obtaining and confirming data from	
21				
22			investigators	05-06
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24	Data items	<a href="#">#12</a>	List and define all variables for which data will be sought	
25				
26			(such as PICO items, funding sources), any pre-planned	
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28			data assumptions and simplifications	
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30	Outcomes and	<a href="#">#13</a>	List and define all outcomes for which data will be sought,	
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32	prioritization		including prioritization of main and additional outcomes, with	
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34			rationale	04-05
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36	Risk of bias in	<a href="#">#14</a>	Describe anticipated methods for assessing risk of bias of	
37				
38	individual studies		individual studies, including whether this will be done at the	
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40			outcome or study level, or both; state how this information	
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42			will be used in data synthesis	06
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44	Data synthesis	<a href="#">#15a</a>	Describe criteria under which study data will be quantitatively	
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46			synthesized	05-06
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1	Data synthesis	<a href="#">#15b</a>	If data are appropriate for quantitative synthesis, describe	
2			planned summary measures, methods of handling data and	
3			methods of combining data from studies, including any	
4			planned exploration of consistency (such as I <sup>2</sup> , Kendall's $\tau$ )	
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13	Data synthesis	<a href="#">#15c</a>	Describe any proposed additional analyses (such as	
14			sensitivity or subgroup analyses, meta-regression)	
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19	Data synthesis	<a href="#">#15d</a>	If quantitative synthesis is not appropriate, describe the type	
20			of summary planned	
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24	Meta-bias(es)	<a href="#">#16</a>	Specify any planned assessment of meta-bias(es) (such as	
25			publication bias across studies, selective reporting within	
26			studies)	
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32	Confidence in	<a href="#">#17</a>	Describe how the strength of the body of evidence will be	
33			assessed (such as GRADE)	
34	cumulative			
35	evidence			
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# BMJ Open

## ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC VENOUS LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL

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<b>Primary Subject Heading</b>:	Nursing
Secondary Subject Heading:	Evidence based practice, Dermatology, Global health
Keywords:	wound healing, Unna Boot, inelastic compression, Leg ulcer, bandagens

SCHOLARONE™  
Manuscripts

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3 **ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC**  
4  
5 **VENOUS LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL**  
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# ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC VENOUS LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL

## ABSTRACT

**Introduction:** Chronic venous insufficiency is an anomaly of the normal functioning of the venous system caused by valvular incompetency with or without obstruction of venous flow. This condition can affect either or both of the superficial and the deep venous systems. Venous dysfunction can even result in congenital or acquired disorders, and its complications include venous leg ulcers. The objective of this systematic review is to determine the effectiveness of Unna Boot in the treatment of wound healing of venous leg ulcers by assessing the quality of the available evidence.

**Methods and analysis:** A literature search in PubMed, CINAHL, Scopus, Web of Science, Cochrane Library, BVS/BIREME, Embase, ProQuest, BDTD, Thesis and Dissertation Catalog, Sao Paulo Research Foundation Research Foundation/Thesis and dissertation, OPEN THESIS, A service of the U.S. National Institute of Health, Center for Reviews and Dissemination-University of New York and SciElo published in the last 10 years. The review will include primary studies (original), and Controlled Trials or Observational studies (cross sectional, case-control or longitudinal studies) with venous leg ulcers. Exclusion will include leg ulceration due to different causes, such as pressure, arterial, diabetic or mixed an etiology leg ulcer. Data synthesis will be performed using a narrative summary and quantitative analysis.

**Ethics and dissemination** This systematic review does not require approval by ethics committee, as individual patient data will not be collected. Dissemination of findings will be through publications in peer-reviewed journal.

**PROSPERO registration number CRD42019127947**

### **Strengths and limitations of this study**

- To know the effectiveness of Unna boot dressing in the management of Venous Leg Ulcers (VLU) will contribute to the use of a low-cost alternative to wound healing. VLUs has not been studied; our systematic review will be the first to answer the question.
- The eligibility criteria used may not result in the selection of studies that are homogeneous in methods, limiting the ability to draw reliable conclusions.
- Limitation: Only article published in English, Spanish and Portuguese will be considered.

### **BACKGROUND**

The VLU cause significant social and economic impact due to their recurrent nature and the long time elapsed between their opening and healing. VLU is a result of venous hypertension caused by chronic venous insufficiency. The consequences of venous insufficiency include edema, dermatitis, hyperpigmentation, skin fibrosis and subcutaneous tissue of the leg and, finally, ulceration (1–4).

Compression therapy is the most important measure of the treatment of a person with VLU because it contributes to the venous return, improving stasis and edema, which translates into better clinical conditions in the lesion and helps shorten the healing time (4–6). Unna Boot is an

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2  
3 inelastic compression therapy that acts to increase compression and promote drainage and venous  
4 support, improving healing of the ulcer (5).  
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7 The compression during rest and muscle contraction, acts on the macrocirculation, increasing the  
8 venous return, and on the tissue pressure, supporting the reabsorption of the edema and the return  
9 of the fluids located in the interstitial spaces to the interior of the vascular and lymphatic system.  
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13 This process promotes the healing of the lesion and prevents inflammation (7–9).  
14

15 The Unna boot consists of a low compression gauze (18-24 mmHg); the composition varies  
16 between the handmade form, which requires previous thermal heating, and the industrial one,  
17 which is ready for use and contains 10% of oxide of zinc, gum acacia, glycerol, castor oil and  
18 deionized water (10,11). According to studies, the use of the Unna boot is effective in promoting  
19 the satisfaction related to minimum wound care, rapid development of granulation tissue,  
20 improvement in comfort and lower costs relative to other compressions that have the same  
21 objective (7,10,12,13).  
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32 This systematic review aims to critically evaluate the effectiveness of Unna Boot on the treatment  
33 of chronic leg ulcers in adults by assessing the quality of the evidence available. Specific  
34 question addressed by the review is: Is the use of Unna Boot effective in the treatment of chronic  
35 leg ulcers in adults?  
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## 42 **METHODS**

43 This protocol has been registered with the PROSPERO (CRD42019127947) and will be reported  
44 following the Preferred Reporting Items for Systematic Review and meta-Analysis Protocols  
45 (PRISMA) (14,15). This review will be report following standardized critical appraisal  
46 instruments from Joanna Briggs Institute (16,17).  
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## 54 **Patient and Public Involvement**



No patients or public were directly involved in the development of this systematic review protocol.

## SEARCH STRATEGIES

We will systematically and electronically conduct searches on the following databases: PubMed (1999- 2019), PubMed/PMC( 1999- 2019), Virtual Health Library (BVS / BIREME) (1999- 2019), The Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1999- 2019), Scopus (1999- 2019), Web of Science (1999-2019), MEDLINE (CAPES) (1999- 2019), Embase (1999- 2019), Cochrane Library (1999- 2019), ProQuest (1999- 2019), Brazilian Digital Library of Theses and Dissertations (BDTD) (1999- 2019), CAPES / Thesis and Dissertation Catalog (1999- 2019) Sao Paulo Research Foundation / Thesis and dissertation (1999-2019), OPEN THESIS (1999- 2019), A service of the U.S. National Institutes of Health (Clinical Trial) (1999- 2019), Centre for Reviews and Dissemination - University of York (1999- 2019), Scientific Electronic Library (SciELO) (1999- 2019).

## SELECTION CRITERIA

All human studies about Unna Boot, treatment that combines zinc oxide paste and compression bandages, for treating VLU will be included.

## STUDY DESIGN

To be included, studies need to be primary (original), Controlled Trials or Observational studies (cross sectional, case-control or longitudinal studies). These studies will be used to assessing the effectiveness of Unna Boot on the healing of VLU. Eligible studies must be in Portuguese, Spanish or English language.

## TYPE OF PARTICIPANTS

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2  
3 The participants are all adult patients with VLU of any location and of size. We will only accept  
4 studies in which authors used ultrasound to confirm wound etiology. The intervention of interest  
5 is Unna boot. We will exclude studies about leg ulceration due to different causes, such as  
6 pressure, arterial, diabetic or mixed etiology leg ulcers.  
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## 10 11 12 **INTERVENTION**

13  
14 The intervention will include Unna boot treatment of VLU. Information about the time of use,  
15 initial wound size, sociodemographic and clinical will be documented.  
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## 18 19 **COMPARATOR**

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21 Studies comparing any other type of dressing, topical agent, placebo or standard treatment will be  
22 included in this review.  
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## 25 26 **OUTCOME MEASURES**

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28 The primary outcome measures are the proportions of wounds with complete healing. We will  
29 consider the proportion of ulcers healed during follow-up and frequency of complete healing  
30 during the study. The rate of adverse effects and events (e.g. the wound infection rate and signs  
31 and symptoms of clinical infection) will be documented. Additional outcome(s), such as Quality  
32 of life (measured using generic questionnaire or a disease-specific questionnaire), and Pain (e.g.  
33 at dressing change or over the course of treatment) will be only included in validated  
34 questionnaires or visual analogue scales. Change in ulcer size will be considered using data on  
35 the change (and percentage change) in ulcer size, with adjustment for baseline size (we will  
36 contact study authors to request adjusted means when not available).  
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## 48 49 **STUDY SELECTION AND DATA MANAGEMENT**

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51 Two review authors will independently assess the titles and abstracts of studies found during the  
52 searches for potential inclusion in this review. Disagreements will be discussed during consensus  
53 meetings with a third review author. Potential relevant studies will be examined in full by two  
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3 review authors. The studies that meet the eligibility criteria will be included in the review.

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5 Disagreements will be discussed at consensus meetings with a third review author.

## 6 7 **DATA EXTRACTION**

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9  
10 For data extraction: extracted information will include the study setting, study characteristics  
11 (authors, year of publication, country of publication, study design), details of the intervention and  
12 control, research design, inclusion and exclusion, outcomes, characteristics of the examined  
13 patient demographics (number of subjects, gender, mean age, comorbidities, number of wounds  
14 treated), wound characteristics (mean wound duration, mean wound size) losses to follow-up,  
15 sensitivity analysis, author conclusions and conflicts of interest. The disease type and stages of  
16 VLU will be identified in the studies, and an attempt will be made to identify whether the second  
17 component of compression was short-stretch or long-stretch bandage. If the attempt fails, at least  
18 it will be discussed. Data extraction will again be performed independently by two reviewers, and  
19 any discrepancies will be resolved through group discussion.

## 20 21 22 **ASSESSMENT OF RISK OF BIAS OF INCLUDED STUDIES**

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25 Two reviewers will independently assess the quality of the included studies by using the  
26 standardized critical appraisal instruments from the Joanna Briggs Institute (JBI) (16,17). The  
27 instruments require the following data: title, authors, year of publication, journal, methodology,  
28 method, data analysis employed, configuration, geographical and cultural context, participants,  
29 interventions, main results and conclusions of authors and reviewers. After extracting the data, a  
30 level of credibility will be assigned to each finding, and the results will be synthesized through  
31 groups of data from primary studies. Disagreements between reviewers over the quality checklist  
32 will be resolved through discussion.

## 33 34 35 **DATA ANALYSIS AND SYNTHESIS**

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3 Data synthesis will be performed using a narrative summary and quantitative analysis. A meta-  
4 analysis considering models of random-effects will be employed to compare among groups based  
5 on outcome variables, if studies included in the review disclose sufficient data.  
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## 10 **DISCUSSION**

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13 This review aims to determine the effectiveness of Unna Boot of the treatment of wound healing  
14 in VLU. This assessment will be performed by evaluating the total proportion of completely  
15 closed wounds relative to that of the start of treatment. Although studies have shown good results  
16 with granulation tissue formation and wound healing (10,18), the effectiveness is currently  
17 unclear. To our knowledge, this is the first systematic review to evaluate the effectiveness of the  
18 Unna boot on wound healing. The result of this review may help health professionals and  
19 educators in the indication of the use of inelastic compression for patients with VLU in reality  
20 where financial resources are scarce.  
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## 31 **AUTHORS CONTRIBUTION**

32 This study was conceptualized by MHML, TP, FCIC, and MGBS, PPA developed the search  
33 strategy. CSBP, MGBS FA completed the search and drafted the protocol. APD, ARSOK,  
34 MGBS and HCO critically appraised the protocol and also contributed to its development by  
35 revising subsequent versions. MHML; ARSOK and HCO will contribute equally to the data  
36 collection and analysis, as well as the interpretation of the review. All authors will revise  
37 critically the review and will read and approved the final manuscript.  
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## 48 **ACKNOWLEDGEMENTS**

49  
50 Not applicable.  
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53  
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55 There is no funding received for this study.  
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## COMPETING INTERESTS

The authors declare that they have no competing interests.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

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# 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-Reporting 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.

			Page
Reporting Item			Number
<b>Title</b>			
Identification	<a href="#">#1a</a>	Identify the report as a protocol of a systematic review	<b>01</b>



- 1 Update [#1b](#) If the protocol is for an update of a previous systematic  
 2 review, identify as such  
 3  
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 6 none  
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- 8 **Registration**
- 9  
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 11 [#2](#) If registered, provide the name of the registry (such as  
 12 PROSPERO) and registration number **CRD42019127947**  
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- 17 **Authors**
- 18  
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 20 Contact [#3a](#) Provide name, institutional affiliation, e-mail address of all  
 21 protocol authors; provide physical mailing address of  
 22 corresponding author **title page**  
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- 28 Contribution [#3b](#) Describe contributions of protocol authors and identify the  
 29 guarantor of the review **09**  
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- 33 **Amendments**
- 34  
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 36 [#4](#) If the protocol represents an amendment of a previously  
 37 completed or published protocol, identify as such and list  
 38 changes; otherwise, state plan for documenting important  
 39 protocol amendments **none**  
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- 46 **Support**
- 47  
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 49 Sources [#5a](#) Indicate sources of financial or other support for the review  
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- 55 Sponsor [#5b](#) Provide name for the review funder and / or sponsor **07**  
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1	Role of sponsor	<a href="#">#5c</a>	Describe roles of funder(s), sponsor(s), and / or institution(s),	
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3	or funder		if any, in developing the protocol	<b>07</b>
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5				
6	<b>Introduction</b>			
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10	Rationale	<a href="#">#6</a>	Describe the rationale for the review in the context of what is	
11			already known	<b>02</b>
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15	Objectives	<a href="#">#7</a>	Provide an explicit statement of the question(s) the review	
16			will address with reference to participants, interventions,	
17			comparators, and outcomes (PICO)	<b>03</b>
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22	<b>Methods</b>			
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26	Eligibility criteria	<a href="#">#8</a>	Specify the study characteristics (such as PICO, study	
27			design, setting, time frame) and report characteristics (such	
28			as years considered, language, publication status) to be	
29			used as criteria for eligibility for the review	
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35				<b>03-04</b>
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38	Information	<a href="#">#9</a>	Describe all intended information sources (such as electronic	
39			databases, contact with study authors, trial registers or other	
40	sources		grey literature sources) with planned dates of coverage	<b>03-</b>
41				<b>04</b>
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48	Search strategy	<a href="#">#10</a>	Present draft of search strategy to be used for at least one	
49			electronic database, including planned limits, such that it	
50			could be repeated	<b>03-04</b>
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1	Study records -	<a href="#">#11a</a>	Describe the mechanism(s) that will be used to manage	
2			records and data throughout the review	04
3	data			
4				
5	management			
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8	Study records -	<a href="#">#11b</a>	State the process that will be used for selecting studies	
9			(such as two independent reviewers) through each phase of	
10	selection process		the review (that is, screening, eligibility and inclusion in	
11			meta-analysis)	04
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16	Study records -	<a href="#">#11c</a>	Describe planned method of extracting data from reports	
17			(such as piloting forms, done independently, in duplicate),	
18	data collection		any processes for obtaining and confirming data from	
19			investigators	05-06
20	process			
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28	Data items	<a href="#">#12</a>	List and define all variables for which data will be sought	
29			(such as PICO items, funding sources), any pre-planned	
30			data assumptions and simplifications	
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36	Outcomes and	<a href="#">#13</a>	List and define all outcomes for which data will be sought,	
37			including prioritization of main and additional outcomes, with	
38	prioritization		rationale	04-05
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44	Risk of bias in	<a href="#">#14</a>	Describe anticipated methods for assessing risk of bias of	
45			individual studies, including whether this will be done at the	
46	individual studies		outcome or study level, or both; state how this information	
47			will be used in data synthesis	06
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54	Data synthesis	<a href="#">#15a</a>	Describe criteria under which study data will be quantitatively	
55			synthesized	05-06
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- 1 Data synthesis [#15b](#) If data are appropriate for quantitative synthesis, describe  
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 4 planned summary measures, methods of handling data and  
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 6 methods of combining data from studies, including any  
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 8 planned exploration of consistency (such as I<sup>2</sup>, Kendall's  $\tau$ )  
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 11 05-06  
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- 13 Data synthesis [#15c](#) Describe any proposed additional analyses (such as  
 14  
 15 sensitivity or subgroup analyses, meta-regression) 05-06  
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- 18 Data synthesis [#15d](#) If quantitative synthesis is not appropriate, describe the type  
 19  
 20 of summary planned 05-06  
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- 24 Meta-bias(es) [#16](#) Specify any planned assessment of meta-bias(es) (such as  
 25  
 26 publication bias across studies, selective reporting within  
 27  
 28 studies) 05-06  
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- 31 Confidence in [#17](#) Describe how the strength of the body of evidence will be  
 32  
 33 cumulative assessed (such as GRADE) 06  
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 35 evidence  
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39 None The PRISMA-P checklist is distributed under the terms of the Creative Commons Attribution  
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 42 made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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# BMJ Open

## ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC VENOUS LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL

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Manuscripts

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3 **ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC**  
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5 **VENOUS LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL**  
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# ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC VENOUS LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL

## ABSTRACT

**Introduction:** Chronic venous insufficiency (CVI) is an anomaly of the normal functioning of the venous system caused by valvular incompetency with or without obstruction of venous flow. This condition can affect either or both of the superficial and the deep venous systems. Venous dysfunction can even result in congenital or acquired disorders, and its complications include venous leg ulcers (VLU). The objective of this systematic review is to determine the effectiveness of Unna Boot in the treatment of wound healing of VLU by assessing the quality of the available evidence.

**Methods and analysis:** A literature search in PubMed, CINAHL, Scopus, Web of Science, Cochrane Library, BVS/BIREME, Embase, ProQuest, BDTD, Thesis and Dissertation Catalog, Sao Paulo Research Foundation Research Foundation/Thesis and dissertation, OPEN THESIS, A service of the U.S. National Institute of Health, Center for Reviews and Dissemination-University of New York and SciElo published in the last 10 years. The review will include primary studies (original), and Controlled Trials or Observational studies (cross sectional, case-control or longitudinal studies) with VLU. Exclusion will include leg ulceration due to different causes, such as pressure, arterial, diabetic or mixed-etiology leg ulcer. Data synthesis will be performed using a narrative summary and quantitative analysis.



**Ethics and dissemination** This systematic review does not require approval by ethics committee, as individual patient data will not be collected. Dissemination of findings will be through publications in peer-reviewed journal and/or via conference presentation.

**PROSPERO registration number CRD42019127947**

### **Strengths and limitations of this study**

- To know the effectiveness of Unna boot dressing in the management of VLU will contribute to the use of a low-cost alternative to wound healing. VLUs has not been studied; our systematic review will be the first to answer the question.
- The eligibility criteria used may not result in the selection of studies that are homogeneous in methods, limiting the ability to draw reliable conclusions.
- Limitation: Only article published in English, Spanish and Portuguese will be considered.

### **BACKGROUND**

CVI is a condition that affects the venous system of the lower limbs, resulting in pain, skin changes, and ulcerations (1). Abnormalities and weaknesses in the surface vein wall may hinder the blood flow from the deepest veins to the heart. In that case, venous valve insufficiency is the main cause of impaired flow in the deep veins of the lower limbs. When this problem occurs, the superficial veins become engorged with blood, and the walls become dilated and permeable to the release of substances normally contained in the vessel (2,3). Deep veins are most affected by acute obstruction (deep vein thrombosis) or chronic damage (stenosis, occlusion) caused by post-thrombotic changes or trauma (4-7).

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2  
3 Acute and chronic deep vein obstruction limits blood flow, resulting in increased venous pressure  
4 with muscle contraction and secondary muscle pump dysfunction (5-8). CVI can be diagnosed  
5 using ultrasound techniques to detect venous reflux and blood accumulation in the deep veins of  
6 the legs (4,5). External compressive therapy is recommended to reverse the high pressure of the  
7 venous system to prevent complications, such as VLU, or to improve venous return to close such  
8 ulcers. (7-9)  
9

10 Compressive therapies can be elastic, inelastic and pneumatic. Among inelastic therapies, there  
11 are several brands available in the market, such as econo-paste® (Hartmann), gelocast (BSN  
12 medical®) Viscopaste® (Smith & Nephew) and Flexdress® (ConvaTec). These products, known  
13 as Unna Boot, are bandages consisting of a low compression gauze (18-24 mmHg) and  
14 impregnated with oxide of zinc, gum acacia, glycerol, castor oil and deionized water, resulting in  
15 a semi-solid mold for external compression (10,11).  
16

17 Unna Boot is an inelastic compression therapy that acts to increase compression and promote  
18 drainage and venous support, improving healing of the ulcer (6,10,11). The compression during  
19 rest and muscle contraction, acts on the macrocirculation, increasing the venous return, and on  
20 the tissue pressure, supporting the reabsorption of the edema and the return of the fluids located  
21 in the interstitial spaces to the interior of the vascular and lymphatic system. This process  
22 promotes the healing of the lesion and prevents inflammation (7-9,11). According to studies, the  
23 use of the Unna boot is effective in promoting the satisfaction related to minimum wound care,  
24 rapid development of granulation tissue, improvement in comfort and cost savings compared to  
25 similar compressions (8,11).  
26

27 This systematic review aims determine the effectiveness of Unna Boot in the treatment of wound  
28 healing of VLU by assessing the quality of the available evidence. Specific question addressed by  
29 the review is: Is the use of Unna Boot effective in the treatment of chronic VLU in adults?  
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## **METHODS**

This protocol has been registered with the PROSPERO (CRD42019127947) and will be reported following the Preferred Reporting Items for Systematic Review and meta-Analysis Protocols (PRISMA) (12,13). This review will be report following standardized critical appraisal instruments from Joanna Briggs Institute (JBI) (14,15).

## **PATIENT AND PUBLIC INVOLVEMENT**

No patients or public were directly involved in the development of this systematic review protocol.

## **SEARCH STRATEGIES**

We will systematically and electronically conduct searches on the following databases: PubMed (1999- 2019), PubMed/PMC( 1999- 2019), Virtual Health Library (BVS / BIREME) (1999- 2019), The Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1999- 2019), Scopus (1999- 2019), Web of Science (1999-2019), MEDLINE (CAPES) (1999- 2019), Embase (1999- 2019), Cochrane Library (1999- 2019), ProQuest (1999- 2019), Brazilian Digital Library of Theses and Dissertations (BDTD) (1999- 2019), CAPES / Thesis and Dissertation Catalog (1999- 2019) Sao Paulo Research Foundation / Thesis and dissertation (1999-2019), OPEN THESIS (1999- 2019), A service of the U.S. National Institutes of Health (Clinical Trial) (1999- 2019), Centre for Reviews and Dissemination - University of York (1999- 2019), Scientific Electronic Library (SciELO) (1999- 2019).

## **SELECTION CRITERIA**

The inclusion criteria will be: All human studies about inelastic compression therapy, treatment that combines zinc oxide paste and compression bandages for treating VLU; medical diagnosis of CVI by Doppler ultrasound examination.

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3 The searches were conducted evaluating the period from January 2006 to January 2019.  
4

## 5 **STUDY DESIGN**

6  
7 To be included, studies need to be primary (original), Controlled Trials or Observational studies  
8  
9 (cross sectional, case-control or longitudinal studies). These studies will be used to assessing the  
10  
11 effectiveness of Unna Boot on the healing of VLU. Eligible studies must be in Portuguese,  
12  
13 Spanish or English language.  
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15

## 16 **TYPE OF PARTICIPANTS**

17  
18 The participants are all adult patients with VLU of any location and size. We will only accept  
19  
20 studies in which authors used Doppler ultrasound to confirm wound etiology. The intervention of  
21  
22 interest is Unna boot. We will exclude studies about leg ulceration of different causes, such as  
23  
24 pressure, arterial, diabetic or mixed etiology leg ulcers.  
25  
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28

## 29 **INTERVENTION**

30  
31 The intervention will include Unna boot treatment of VLU. Information about the time of use,  
32  
33 initial wound size, sociodemographic and clinical will be documented.  
34  
35

## 36 **COMPARATOR**

37  
38 Studies comparing any other type of dressing, topical agent, placebo or standard treatment will be  
39  
40 included in this review.  
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42

## 43 **OUTCOME MEASURES**

44  
45 The primary outcome measures are the proportions of wounds with complete healing. We will  
46  
47 consider the proportion of ulcers healed during follow-up and frequency of complete healing  
48  
49 during the study. The rate of adverse effects and events (e.g. the wound infection rate and signs  
50  
51 and symptoms of clinical infection) will be documented. Additional outcome(s), such as Quality  
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53 of life (measured using generic questionnaire or a disease-specific questionnaire), and Pain (e.g.  
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3 at dressing change or over the course of treatment) will be only included in validated  
4 questionnaires or visual analogue scales. Change in ulcer size will be considered using data on  
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6  
7 the change (and percentage change) in ulcer size, with adjustment for baseline size (we will  
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9  
10 contact study authors to request adjusted means when not available).

## 11 12 **STUDY SELECTION AND DATA MANAGEMENT**

13  
14 Two review authors will independently assess the titles and abstracts of studies found during the  
15  
16 searches for potential inclusion in this review. Disagreements will be discussed during consensus  
17  
18 meetings with a third review author. Potentially relevant studies will be examined in full by two  
19  
20 review authors. The studies that meet the eligibility criteria will be included in the review.  
21  
22  
23 Disagreements will be discussed in consensus meetings with a third review author.

## 24 25 26 **DATA EXTRACTION**

27  
28 For data extraction: extracted information will include the study setting, study characteristics  
29  
30 (authors, year of publication, country of publication, study design), details of the intervention and  
31  
32 control, research design, inclusion and exclusion, outcomes, characteristics of the examined  
33  
34 patient demographics (number of subjects, gender, mean age, comorbidities, number of wounds  
35  
36 treated), wound characteristics (mean wound duration, mean wound size) losses to follow-up,  
37  
38 sensitivity analysis, author conclusions and conflicts of interest. The disease type and stages of  
39  
40 VLU will be identified in the studies by clinical, etiological, anatomical and pathological  
41  
42 elements (CEAP) for classification of chronic venous insufficiency (4), and an attempt will be  
43  
44 made to identify whether the second component of compression was short-stretch or long-stretch  
45  
46 bandage. The origin of the ulcer will be identified and grouped in primary, post-thrombotic  
47  
48 disease and recurrent as needed. If the attempt fails, at least it will be discussed. Data extraction  
49  
50 will again be performed independently by two reviewers, and any discrepancies will be resolved  
51  
52 through group discussion.  
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## ASSESSMENT OF RISK OF BIAS OF INCLUDED STUDIES

Two reviewers will independently assess the quality of the included studies by using the standardized critical appraisal instruments from the JBI (14,15). The instruments require the following data: title, authors, year of publication, journal, methodology, method, data analysis employed, configuration, geographical and cultural context, participants, interventions, main results and conclusions of authors and reviewers. After extracting the data, a level of credibility will be assigned to each finding, and the results will be synthesized through groups of data from primary studies. Disagreements between reviewers over the quality checklist will be resolved through discussion.

## DATA ANALYSIS AND SYNTHESIS

Data synthesis will be performed using a narrative summary and quantitative analysis. A meta-analysis considering models of random-effects will be employed to compare among groups based on outcome variables, if studies included in the review disclose sufficient data.

## DISCUSSION

This review aims to determine the effectiveness of Unna Boot of the treatment of wound healing in VLU. This assessment will be performed by evaluating the total proportion of completely closed wounds relative to that of the start of treatment. Although studies have shown good results with granulation tissue formation and wound healing (11,16), the effectiveness is currently unclear. To our knowledge, this is the first systematic review to evaluate the effectiveness of the Unna boot on wound healing. The result of this review may help health professionals and educators recommend the use of inelastic compression for patients with VLU, especially where financial resources are scarce.

## **AUTHORS CONTRIBUTION**

This study was conceptualized by MHML, TP, FCIC, and MGBS, PPA developed the search strategy. CSBP, MGBS, FA completed the search and drafted the protocol. APD, ARSO-K, MGBS and HCO critically appraised the protocol and also contributed to its development by revising subsequent versions. MHML; ARSO-K and HCO will contribute equally to the data collection and analysis, as well as the interpretation of the review. All authors will revise critically the review and will read and approved the final manuscript.

## **ACKNOWLEDGEMENTS**

Not applicable.

## **FUNDING**

No funding was received for this study.

## **COMPETING INTERESTS**

The authors declare that they have no competing interests.

## **ETHICS AND DISSEMINATION**

This systematic review does not require approval by ethics committee, as individual patient data will not be collected. Dissemination of findings will be through publications in peer-reviewed journal and/or via conference presentation.

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# 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-Reporting 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.

			Page
Reporting Item			Number
<b>Title</b>			
Identification	<a href="#">#1a</a>	Identify the report as a protocol of a systematic review	<b>01</b>

- 1 Update [#1b](#) If the protocol is for an update of a previous systematic  
 2 review, identify as such  
 3  
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 6 none  
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- 8  
 9 **Registration**  
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 12 [#2](#) If registered, provide the name of the registry (such as  
 13 PROSPERO) and registration number **CRD42019127947**  
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- 17 **Authors**  
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 20 Contact [#3a](#) Provide name, institutional affiliation, e-mail address of all  
 21 protocol authors; provide physical mailing address of  
 22 corresponding author **title page**  
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- 28 Contribution [#3b](#) Describe contributions of protocol authors and identify the  
 29 guarantor of the review **09**  
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- 33 **Amendments**  
 34  
 35  
 36 [#4](#) If the protocol represents an amendment of a previously  
 37 completed or published protocol, identify as such and list  
 38 changes; otherwise, state plan for documenting important  
 39 protocol amendments **none**  
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- 46 **Support**  
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 49 Sources [#5a](#) Indicate sources of financial or other support for the review  
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 51 **07**  
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- 55 Sponsor [#5b](#) Provide name for the review funder and / or sponsor **07**  
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1	Role of sponsor	<a href="#">#5c</a>	Describe roles of funder(s), sponsor(s), and / or institution(s),	
2				
3	or funder		if any, in developing the protocol	<b>07</b>
4				
5				
6	<b>Introduction</b>			
7				
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10	Rationale	<a href="#">#6</a>	Describe the rationale for the review in the context of what is	
11			already known	<b>02</b>
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14				
15	Objectives	<a href="#">#7</a>	Provide an explicit statement of the question(s) the review	
16			will address with reference to participants, interventions,	
17			comparators, and outcomes (PICO)	<b>03</b>
18				
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22	<b>Methods</b>			
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26	Eligibility criteria	<a href="#">#8</a>	Specify the study characteristics (such as PICO, study	
27			design, setting, time frame) and report characteristics (such	
28			as years considered, language, publication status) to be	
29			used as criteria for eligibility for the review	
30				<b>03-04</b>
31				
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38	Information	<a href="#">#9</a>	Describe all intended information sources (such as electronic	
39			databases, contact with study authors, trial registers or other	
40	sources		grey literature sources) with planned dates of coverage	<b>03-</b>
41				<b>04</b>
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48	Search strategy	<a href="#">#10</a>	Present draft of search strategy to be used for at least one	
49			electronic database, including planned limits, such that it	
50			could be repeated	<b>03-04</b>
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1	Study records -	<a href="#">#11a</a>	Describe the mechanism(s) that will be used to manage	
2			records and data throughout the review	04
3	data			
4				
5	management			
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8	Study records -	<a href="#">#11b</a>	State the process that will be used for selecting studies	
9			(such as two independent reviewers) through each phase of	
10	selection process		the review (that is, screening, eligibility and inclusion in	
11			meta-analysis)	04
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18	Study records -	<a href="#">#11c</a>	Describe planned method of extracting data from reports	
19			(such as piloting forms, done independently, in duplicate),	
20	data collection		any processes for obtaining and confirming data from	
21			investigators	05-06
22	process			
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28	Data items	<a href="#">#12</a>	List and define all variables for which data will be sought	
29			(such as PICO items, funding sources), any pre-planned	
30			data assumptions and simplifications	
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36	Outcomes and	<a href="#">#13</a>	List and define all outcomes for which data will be sought,	
37			including prioritization of main and additional outcomes, with	
38	prioritization		rationale	04-05
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44	Risk of bias in	<a href="#">#14</a>	Describe anticipated methods for assessing risk of bias of	
45			individual studies, including whether this will be done at the	
46	individual studies		outcome or study level, or both; state how this information	
47			will be used in data synthesis	06
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54	Data synthesis	<a href="#">#15a</a>	Describe criteria under which study data will be quantitatively	
55			synthesized	05-06
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1	Data synthesis	<a href="#">#15b</a>	If data are appropriate for quantitative synthesis, describe	
2			planned summary measures, methods of handling data and	
3			methods of combining data from studies, including any	
4			planned exploration of consistency (such as I <sup>2</sup> , Kendall's $\tau$ )	
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11				<b>05-06</b>
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13	Data synthesis	<a href="#">#15c</a>	Describe any proposed additional analyses (such as	
14			sensitivity or subgroup analyses, meta-regression)	
15				<b>05-06</b>
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18	Data synthesis	<a href="#">#15d</a>	If quantitative synthesis is not appropriate, describe the type	
19			of summary planned	
20				<b>05-06</b>
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24	Meta-bias(es)	<a href="#">#16</a>	Specify any planned assessment of meta-bias(es) (such as	
25			publication bias across studies, selective reporting within	
26			studies)	
27				<b>05-06</b>
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30				
31	Confidence in	<a href="#">#17</a>	Describe how the strength of the body of evidence will be	
32			assessed (such as GRADE)	
33	cumulative			<b>06</b>
34	evidence			
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39 None The PRISMA-P checklist is distributed under the terms of the Creative Commons Attribution

40 License CC-BY 4.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool

41 made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

# BMJ Open

## ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC VENOUS LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL

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Manuscripts

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3 **ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC**  
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5 **VENOUS LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL**  
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# ASSESSMENT OF THE USE OF UNNA BOOT IN THE TREATMENT OF CHRONIC VENOUS LEG ULCERS IN ADULTS: SYSTEMATIC REVIEW PROTOCOL

## ABSTRACT

**Introduction:** Chronic venous insufficiency (CVI) is an anomaly of the normal functioning of the venous system caused by valvular incompetency with or without obstruction of venous flow. This condition can affect either or both of the superficial and the deep venous systems. Venous dysfunction can even result in congenital or acquired disorders, and its complications include venous leg ulcers (VLU). The objective of this systematic review is to determine the effectiveness of Unna Boot in the treatment of wound healing of VLU by assessing the quality of the available evidence.

**Methods and analysis:** A literature search in PubMed, CINAHL, Scopus, Web of Science, Cochrane Library, BVS/BIREME, Embase, ProQuest, BDTD, Thesis and Dissertation Catalog, Sao Paulo Research Foundation Research Foundation/Thesis and dissertation, OPEN THESIS, A service of the U.S. National Institute of Health, Center for Reviews and Dissemination-University of New York and SciElo published in the last 10 years, the period from January 1999 to March 2019. The review will include primary studies (original), and Controlled Trials or Observational studies (cross sectional, case-control or longitudinal studies) with VLU. Exclusion will include leg ulceration due to different causes, such as pressure, arterial, diabetic or mixed-etiology leg ulcer. Data synthesis will be performed using a narrative summary and quantitative analysis.

**Ethics and dissemination** This systematic review does not require approval by ethics committee, as individual patient data will not be collected. Dissemination of findings will be through publications in peer-reviewed journals and/or via conference presentation.

**PROSPERO registration number CRD42019127947**

### **Strengths and limitations of this study**

- Knowing the effectiveness of Unna boot dressing in the management of VLU will contribute to the use of a low-cost alternative to wound healing. VLUs has not been studied; our systematic review will be the first to answer the question.
- The eligibility criteria used may not result in the selection of studies that are homogeneous in methods, limiting the ability to draw reliable conclusions.
- Limitation: Only article published in English, Spanish and Portuguese will be considered.

### **BACKGROUND**

CVI is a condition that affects the venous system of the lower limbs, resulting in pain, skin changes and ulcerations (1). Abnormalities and weaknesses in the surface vein wall may hinder the blood flow from the deepest veins to the heart. In that case, venous valve insufficiency is the main cause of impaired flow in the deep veins of the lower limbs. When this problem occurs, the superficial veins become engorged with blood, and the walls become dilated and permeable to the release of substances normally contained in the vessel (2,3). Deep veins are most affected by acute obstruction (deep vein thrombosis) or chronic damage (stenosis, occlusion) caused by post-thrombotic changes or trauma (4-7).

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3 Acute and chronic deep vein obstruction limits blood flow, resulting in increased venous pressure  
4 with muscle contraction and secondary muscle pump dysfunction (5-8). CVI can be diagnosed  
5 using ultrasound techniques to detect venous reflux and blood accumulation in the deep veins of  
6 the legs (4,5). External compressive therapy is recommended to reverse the high pressure of the  
7 venous system to prevent complications, such as VLU, or to improve venous return to close such  
8 ulcers. (7-9).  
9

10 Compressive therapies can be elastic, inelastic and pneumatic. Among inelastic therapies, there  
11 are several brands available in the market, such as econo-paste® (Hartmann), gelocast (BSN  
12 medical®) Viscopaste® (Smith & Nephew) and Flexdress® (ConvaTec). These products, known  
13 as Unna Boot, are bandages consisting of a low compression gauze (18-24 mmHg) and  
14 impregnated with oxide of zinc, gum acacia, glycerol, castor oil, and deionized water, resulting  
15 in a semi-solid mold for external compression (10,11).  
16

17 Unna Boot is an inelastic compression therapy that acts to increase compression and promote  
18 drainage and venous support, improving healing of the ulcer (6,10,11). The compression, during  
19 rest and muscle contraction, acts on the macrocirculation, increasing the venous return, and on  
20 the tissue pressure, supporting the reabsorption of the edema and the return of the fluids located  
21 in the interstitial spaces to the interior of the vascular and lymphatic system. This process  
22 promotes the healing of the lesion and prevents inflammation (7-9,11). According to studies, the  
23 use of the Unna boot is effective in promoting the satisfaction related to minimum wound care,  
24 rapid development of granulation tissue, improvement in comfort and cost savings compared to  
25 similar compressions (8,11).  
26

27 This systematic review aims to determine the effectiveness of Unna Boot in the treatment of  
28 wound healing of VLU by assessing the quality of the available evidence. Specific question  
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3 addressed by the review is: Is the use of Unna Boot effective in the treatment of chronic VLU in  
4  
5 adults?  
6

## 7 **METHODS**

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9  
10 This protocol has been registered with the PROSPERO (CRD42019127947) and will be reported  
11  
12 following the Preferred Reporting Items for Systematic Review and meta-Analysis Protocols  
13  
14 (PRISMA) (12,13). This review will be report following standardized critical appraisal  
15  
16 instruments from Joanna Briggs Institute (JBI) (14,15).  
17  
18

## 19 **PATIENT AND PUBLIC INVOLVEMENT**

20  
21 No patients nor the general public were directly involved in the development of this systematic  
22  
23 review protocol.  
24  
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26

## 27 **SEARCH STRATEGIES**

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29 We will systematically and electronically conduct searches on the following databases: PubMed  
30  
31 (1999- 2019), PubMed/PMC( 1999- 2019), Virtual Health Library (BVS / BIREME) (1999-  
32  
33 2019), The Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1999- 2019),  
34  
35 Scopus (1999- 2019), Web of Science (1999-2019), MEDLINE (CAPES) (1999- 2019), Embase  
36  
37 (1999- 2019), Cochrane Library (1999- 2019), ProQuest (1999- 2019), Brazilian Digital Library  
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39 of Theses and Dissertations (BDTD) (1999- 2019), CAPES / Thesis and Dissertation Catalog  
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41 (1999- 2019) Sao Paulo Research Foundation / Thesis and dissertation (1999-2019), OPEN  
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43 THESIS (1999- 2019), A service of the U.S. National Institutes of Health (Clinical Trial) (1999-  
44  
45 2019), Centre for Reviews and Dissemination - University of York (1999- 2019), Scientific  
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47 Electronic Library (SciELO) (1999- 2019). The full search strategy is displayed in online  
48  
49 supplementary file (appendix 1).  
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## 55 **SELECTION CRITERIA**

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3 The inclusion criteria will be: All human studies about inelastic compression therapy, treatment  
4 that combines zinc oxide paste and compression bandages for treating VLU, and in which  
5  
6 medical diagnosis of CVI by Doppler ultrasound examination was used.  
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9  
10 The searches were conducted evaluating the period from January 1999 to March 2019.  
11

## 12 **STUDY DESIGN**

13  
14 To be included, studies need to be primary (original), Controlled Trials or Observational studies  
15  
16 (cross sectional, case-control or longitudinal studies). These studies will be used to assessing the  
17  
18 effectiveness of Unna Boot on the healing of VLU. Eligible studies must be in Portuguese,  
19  
20 Spanish or English language.  
21  
22

## 23 **TYPE OF PARTICIPANTS**

24  
25 The participants are all adult patients with VLU of any location and size. We will only accept  
26  
27 studies in which authors used Doppler ultrasound to confirm wound etiology. The intervention of  
28  
29 interest is Unna boot. We will exclude studies about leg ulceration of different causes, such as  
30  
31 pressure, arterial, diabetic or mixed etiology leg ulcers.  
32  
33

## 34 **INTERVENTION**

35  
36 The intervention will include Unna boot treatment of VLU. Information about the time of use,  
37  
38 initial wound size, sociodemographic and clinical will be documented.  
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41

## 42 **COMPARATOR**

43  
44 Studies comparing any other type of dressing, topical agent, placebo or standard treatment will be  
45  
46 included in this review.  
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48

## 49 **OUTCOME MEASURES**

50  
51 The primary outcome measures are the proportions of wounds with complete healing. We will  
52  
53 consider the proportion of ulcers healed during follow-up and frequency of complete healing  
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3 during the study. The rate of adverse effects and events (e.g. the wound infection rate and signs  
4 and symptoms of clinical infection) will be documented. Additional outcome(s), such as Quality  
5 of life (measured using generic questionnaire or a disease-specific questionnaire), and Pain (e.g.  
6 at dressing change or over the course of treatment) will be only included in validated  
7 questionnaires or visual analogue scales. Change in ulcer size will be considered using data on  
8 the change (and percentage change) in ulcer size, with adjustment for baseline size (we will  
9 contact study authors to request adjusted means when not available).

## 18 **STUDY SELECTION AND DATA MANAGEMENT**

21 Two review authors will independently assess the titles and abstracts of studies found during the  
22 searches for potential inclusion in this review. Disagreements will be discussed during consensus  
23 meetings with a third review author. Potentially relevant studies will be examined in full by two  
24 review authors. The studies that meet the eligibility criteria will be included in the review.  
25 Disagreements will be discussed in consensus meetings with a third review author.

## 32 **DATA EXTRACTION**

35 For data extraction: extracted information will include the study setting, study characteristics  
36 (authors, year of publication, country of publication, study design), details of the intervention and  
37 control, research design, inclusion and exclusion, outcomes, characteristics of the examined  
38 patient demographics (number of subjects, gender, mean age, comorbidities, number of wounds  
39 treated), wound characteristics (mean wound duration, mean wound size) losses to follow-up,  
40 sensitivity analysis, author conclusions and conflicts of interest. The disease type and stages of  
41 VLU will be identified in the studies by clinical, etiological, anatomical and pathological  
42 elements (CEAP) for classification of chronic venous insufficiency (4), and an attempt will be  
43 made to identify whether the second component of compression was short-stretch or long-stretch  
44 bandage. The origin of the ulcer will be identified and grouped in primary, post-thrombotic  
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3 disease and recurrent as needed. Failed attempts will be discussed. Data extraction will again be  
4  
5 performed independently by two reviewers, and any discrepancies will be resolved through group  
6  
7 discussion.  
8

### 9 10 **ASSESSMENT OF RISK OF BIAS OF INCLUDED STUDIES**

11  
12 Two reviewers will independently assess the quality of the included studies by using the  
13  
14 standardized critical appraisal instruments from the JBI (14,15). The instruments require the  
15  
16 following data: title, authors, year of publication, journal, methodology, method, data analysis  
17  
18 employed, configuration, geographical and cultural context, participants, interventions, main  
19  
20 results and conclusions of authors and reviewers. After extracting the data, a level of credibility  
21  
22 will be assigned to each finding, and the results will be synthesized through groups of data from  
23  
24 primary studies. Disagreements between reviewers over the quality checklist will be resolved  
25  
26 through discussion.  
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### 30 31 **DATA ANALYSIS AND SYNTHESIS**

32  
33 Data synthesis will be performed using a narrative summary and quantitative analysis. A meta-  
34  
35 analysis considering models of random-effects will be employed to compare among groups based  
36  
37 on outcome variables, if studies included in the review disclose sufficient data.  
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39

### 40 41 **DISCUSSION**

42  
43 This review aims to determine the effectiveness of Unna Boot of the treatment of wound healing  
44  
45 in VLU. This assessment will be performed by evaluating the total proportion of completely  
46  
47 closed wounds relative to that of the start of treatment. Although studies have shown good results  
48  
49 with granulation tissue formation and wound healing (11,16), the effectiveness is currently  
50  
51 unclear. To our knowledge, this is the first systematic review to evaluate the effectiveness of the  
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53 Unna boot on wound healing. The result of this review may help health professionals and  
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educators recommend the use of inelastic compression for patients with VLU, especially where financial resources are scarce.

## **AUTHORS CONTRIBUTION**

This study was conceptualized by MHML, TP, FCIC, and MGBS, PPA developed the search strategy. CSBP, MGBS, FA completed the search and drafted the protocol. APD, ARSO-K, MGBS and HCO critically appraised the protocol and also contributed to its development by revising subsequent versions. MHML; ARSO-K and HCO will contribute equally to the data collection and analysis, as well as the interpretation of the review. All authors will revise critically the review and will read and approved the final manuscript.

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Not applicable.

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## **COMPETING INTERESTS**

The authors declare that they have no competing interests.

## **ETHICS AND DISSEMINATION**

This systematic review does not require approval by ethics committee, as individual patient data will not be collected. Dissemination of findings will be through publications in peer-reviewed journals and/or via conference presentation.

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3 PubMed/PMC: ((((((("Unna Boot") OR "Unna's boot") OR "Unna's paste") OR "Unna  
4 paste"))) AND (((((Wound Healing[MeSH Terms]) OR "Wound  
5 Healing"[Title/Abstract]) OR "Healing, Wound"[Title/Abstract]) OR "Healings,  
6 Wound"[Title/Abstract]) OR "Wound Healings"[Title/Abstract])) AND  
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8 (((((((((((((((((((((((((Varicose Ulcer[MeSH Terms]) OR "Varicose  
9 Ulcer"[Title/Abstract]) OR "Ulcer, Varicose"[Title/Abstract]) OR "Ulcers,  
10 Varicose"[Title/Abstract]) OR "Varicose Ulcers"[Title/Abstract]) OR "Venous Stasis  
11 Ulcers"[Title/Abstract]) OR "Stasis Ulcer, Venous"[Title/Abstract]) OR "Stasis Ulcers,  
12 Venous"[Title/Abstract]) OR "Ulcer, Venous Stasis"[Title/Abstract]) OR "Ulcers,  
13 Venous Stasis"[Title/Abstract]) OR "Venous Stasis Ulcer"[Title/Abstract]) OR "Venous  
14 Hypertension Ulcers"[Title/Abstract]) OR "Hypertension Ulcer,  
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16 "Ulcer, Venous Hypertension"[Title/Abstract]) OR "Ulcers, Venous  
17 Hypertension"[Title/Abstract]) OR "Venous Hypertension Ulcer"[Title/Abstract]) OR  
18 "Venous Ulcer"[Title/Abstract]) OR "Ulcer, Venous"[Title/Abstract]) OR "Ulcers,  
19 Venous"[Title/Abstract]) OR "Venous Ulcers"[Title/Abstract]) OR "Stasis  
20 Ulcer"[Title/Abstract]) OR "Stasis Ulcers"[Title/Abstract]) OR "Ulcer,  
21 Stasis"[Title/Abstract]) OR "Ulcers, Stasis"[Title/Abstract])),

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36 Virtual Health Library (BVS / BIREME): (tw:("Unna Boot" OR "Unna's boot" OR  
37 "Unna's paste" OR "Unna paste" OR "Bota de Unna" OR "Bota de Unna")) AND  
38 (tw:("Wound Healing" OR "Cicatrización de Heridas" OR cicatrização)) AND  
39 (tw:("Varicose Ulcer" OR "Úlcera Varicosa" OR "Úlcera Varicosa")) AND  
40 (instance:"regional"),  
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46 CINAHL: "Unna Boot" OR "Unna's boot" OR "Unna's paste" OR "Unna paste" AND  
47 (MH "Wound Healing") OR "Wound Healing" OR "Healing, Wound" OR "Healings,  
48 Wound" OR "Wound Healings" AND (MH "Venous Ulcer") OR Varicose Ulcer OR  
49 "Ulcer, Varicose" OR "Ulcers, Varicose" OR "Varicose Ulcers" OR "Venous Stasis  
50 Ulcers" OR "Stasis Ulcer, Venous" OR "Stasis Ulcers, Venous" OR "Ulcer, Venous  
51 Stasis" OR "Ulcers, Venous Stasis" OR "Venous Stasis Ulcer" OR "Venous  
52 Hypertension Ulcers" OR "Hypertension Ulcer, Venous" OR "Hypertension Ulcers,  
53 Venous" OR "Ulcer, Venous Hypertension" OR "Ulcers, Venous Hypertension" OR  
54 "Venous Hypertension Ulcer" OR "Venous Ulcer Ulcer, Venous" OR "Ulcers, Venous"

OR "Venous Ulcers" OR "Stasis Ulcer" OR "Stasis Ulcers" OR "Ulcer, Stasis" OR "Ulcers, Stasis",

Scopus: ( ( ALL ( "Unna Boot" OR "Unna's boot" OR "Unna's paste" OR "Unna paste" ) ) AND ( TITLE-ABS-KEY ( bandages OR bandage OR dressings OR dressing ) ) ) AND ( TITLE-ABS-KEY ( "Wound Healing" OR "Healing, Wound" OR "Healings, Wound" OR "Wound Healings" ) ) AND ( TITLE-ABS-KEY ( "Varicose Ulcer" OR "Ulcer, Varicose" OR "Ulcers, Varicose" OR "Varicose Ulcers" OR "Venous Stasis Ulcers" OR "Stasis Ulcer, Venous" OR "Stasis Ulcers, Venous" OR "Ulcer, Venous Stasis" OR "Ulcers, Venous Stasis" OR "Venous Stasis Ulcer" OR "Venous Hypertension Ulcers" OR "Hypertension Ulcer, Venous" OR "Hypertension Ulcers, Venous" OR "Ulcer, Venous Hypertension" OR "Ulcers, Venous Hypertension" OR "Venous Hypertension Ulcer" OR "Venous Ulcer Ulcer, Venous" OR "Ulcers, Venous" OR "Venous Ulcers" OR "Stasis Ulcer" OR "Stasis Ulcers" OR "Ulcer, Stasis" OR "Ulcers, Stasis" ) ) ),

WEB OF SCIENCE: TÓPICO: ("Unna Boot" OR "Unna's boot" OR "Unna's paste" OR "Unna paste") Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos AND TÓPICO: ("Wound Healing" OR "Healing, Wound" OR "Healings, Wound" OR "Wound Healings") Índices=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI Tempo estipulado=Todos os anos AND TÓPICO: ("Varicose Ulcer" OR "Ulcer, Varicose" OR "Ulcers, Varicose" OR "Varicose Ulcers" OR "Venous Stasis Ulcers" OR "Stasis Ulcer, Venous" OR "Stasis Ulcers, Venous" OR "Ulcer, Venous Stasis" OR "Ulcers, Venous Stasis" OR "Venous Stasis Ulcer" OR "Venous Hypertension Ulcers" OR "Hypertension Ulcer, Venous" OR "Hypertension Ulcers, Venous" OR "Ulcer, Venous Hypertension" OR "Ulcers, Venous Hypertension" OR "Venous Hypertension Ulcer" OR "Venous Ulcer Ulcer, Venous" OR "Ulcers, Venous" OR "Venous Ulcers" OR "Stasis Ulcer" OR "Stasis Ulcers" OR "Ulcer, Stasis" OR "Ulcers, Stasis")

MEDLINE (CAPES): ("Unna Boot" or "Unna's boot" or "Unna's paste" or "Unna paste").af. AND Wound Healing.mp. or exp \*Wound Healing/ OR ("Wound Healing" or "Healing, Wound" or "Healings, Wound" or "Wound Healings").af. AND "Varicose Ulcer".mp. or exp \*Varicose Ulcer/ OR ("Varicose Ulcer" or "Ulcer, Varicose" or

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3 "Ulcers, Varicose" or "Varicose Ulcers" or "Venous Stasis Ulcers" or "Stasis Ulcer,  
4 Venous" or "Stasis Ulcers, Venous" or "Ulcer, Venous Stasis" or "Ulcers, Venous  
5 Stasis" or "Venous Stasis Ulcer" or "Venous Hypertension Ulcers" or "Hypertension  
6 Ulcer, Venous" or "Hypertension Ulcers, Venous" or "Ulcer, Venous Hypertension" or  
7 "Ulcers, Venous Hypertension" or "Venous Hypertension Ulcer" or "Venous Ulcer  
8 Ulcer, Venous" or "Ulcers, Venous" or "Venous Ulcers" or "Stasis Ulcer" or "Stasis  
9 Ulcers" or "Ulcer, Stasis" or "Ulcers, Stasis"),

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17 Embase: ('unna boot'/exp OR 'unna boot'/syn OR 'unna boot':ti,ab,kw) AND ('wound  
18 healing'/exp OR 'wound healing'/syn OR 'wound healing':ti,ab,kw) AND ('varicosis'/exp  
19 OR 'varicosis'/syn OR 'varicosis'),

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24 Cochrane Library: ("Unna Boot" OR "Unna's boot" OR "Unna's paste" OR "Unna  
25 paste" OR "Bota de Unna") OR ("Unna Boot" OR "Unna's boot" OR "Unna's paste" OR  
26 "Unna paste" OR "Bota de Unna"):ti,ab,kw) AND ("wound healing" OR "healing,  
27 wound" OR "healings, wound" OR "wound healings") OR ("wound healing" OR  
28 "healing, wound" OR "healings, wound" OR "wound healings"):ti,ab,kw) AND  
29 ("Varicose Ulcer" OR "Ulcer, Varicose" OR "Ulcers, Varicose" OR "Varicose Ulcers"  
30 OR "Venous Stasis Ulcers" OR "Stasis Ulcer, Venous" OR "Stasis Ulcers, Venous" OR  
31 "Ulcer, Venous Stasis" OR "Ulcers, Venous Stasis" OR "Venous Stasis Ulcer" OR  
32 "Venous Hypertension Ulcers" OR "Hypertension Ulcer, Venous" OR "Hypertension  
33 Ulcers, Venous" OR "Ulcer, Venous Hypertension" OR "Ulcers, Venous Hypertension"  
34 OR "Venous Hypertension Ulcer" OR "Venous Ulcer Ulcer, Venous" OR "Ulcers,  
35 Venous" OR "Venous Ulcers" OR "Stasis Ulcer" OR "Stasis Ulcers" OR "Ulcer, Stasis"  
36 OR "Ulcers, Stasis") OR ("Varicose Ulcer" OR "Ulcer, Varicose" OR "Ulcers,  
37 Varicose" OR "Varicose Ulcers" OR "Venous Stasis Ulcers" OR "Stasis Ulcer, Venous"  
38 OR "Stasis Ulcers, Venous" OR "Ulcer, Venous Stasis" OR "Ulcers, Venous Stasis" OR  
39 "Venous Stasis Ulcer" OR "Venous Hypertension Ulcers" OR "Hypertension Ulcer,  
40 Venous" OR "Hypertension Ulcers, Venous" OR "Ulcer, Venous Hypertension" OR  
41 "Ulcers, Venous Hypertension" OR "Venous Hypertension Ulcer" OR "Venous  
42 UlcerUlcer, Venous" OR "Ulcers, Venous" OR "Venous Ulcers" OR "Stasis Ulcer" OR  
43 "Stasis Ulcers" OR "Ulcer, Stasis" OR "Ulcers, Stasis"),



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3 ProQuest:("Unna Boot" OR "Unna's boot" OR "Unna's paste" ) AND ("Wound  
4 Healing" OR "Healing, Wound" OR "Healings, Wound" OR "Wound Healings") AND  
5 ("Varicose Ulcer" OR "Ulcer, Varicose" OR "Ulcers, Varicose" OR "Varicose Ulcers"  
6 OR "Venous Stasis Ulcers" OR "Stasis Ulcer, Venous" OR "Stasis Ulcers, Venous" OR  
7 "Ulcer, Venous Stasis" OR "Ulcers, Venous Stasis" OR "Venous Stasis Ulcer" OR  
8 "Venous Hypertension Ulcers" OR "Hypertension Ulcer, Venous" OR "Hypertension  
9 Ulcers, Venous" OR "Ulcer, Venous Hypertension" OR "Ulcers, Venous Hypertension"  
10 OR "Venous Hypertension Ulcer" OR "Venous Ulcer Ulcer, Venous" OR "Ulcers,  
11 Venous" OR "Venous Ulcers" OR "Stasis Ulcer" OR "Stasis Ulcers" OR "Ulcer, Stasis"  
12 OR "Ulcers, Stasis")

13 BDTD:"Bota de Unna" AND Cicatrização AND "Úlcera Varicosa",

14 Thesis and Dissertation Catalog: "Bota de Unna" AND Cicatrização AND "Úlcera  
15 Varicosa",

16 Sao Paulo Research Foundation/ Thesis and dissertation: "Bota de Unna" AND  
17 Cicatrização AND "Úlcera Varicosa",

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31 OPEN THESIS: ("Unna Boot" OR "Unna's boot" OR "Unna's paste" OR "Unna paste")  
32 AND "Wound Healing" AND "Varicose Ulcer", Clinical Trial:"Unna Boot" OR  
33 "Unna's boot" OR "Unna's paste" OR "Unna paste" AND "Wound Healing" AND  
34 "Varicose Ulcer",

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Centre for Reviews and Dissemination - University of York: ("Unna Boot" OR "Unna's  
boot" OR "Unna's paste" OR "Unna paste" ) AND ("Wound Healing" OR "Healing,  
Wound" OR "Healings, Wound" OR "Wound Healings") AND ("Varicose Ulcer" OR  
"Ulcer, Varicose" OR "Ulcers, Varicose" OR "Varicose Ulcers" OR "Venous Stasis  
Ulcers" OR "Stasis Ulcer, Venous" OR "Stasis Ulcers, Venous" OR "Ulcer, Venous  
Stasis" OR "Ulcers, Venous Stasis" OR "Venous Stasis Ulcer" OR "Venous  
Hypertension Ulcers" OR "Hypertension Ulcer, Venous" OR "Hypertension Ulcers,  
Venous" OR "Ulcer, Venous Hypertension" OR "Ulcers, Venous Hypertension" OR  
"Venous Hypertension Ulcer" OR "Venous UlcerUlcer, Venous" OR "Ulcers, Venous"  
OR "Venous Ulcers" OR "Stasis Ulcer" OR "Stasis Ulcers" OR "Ulcer, Stasis" OR  
"Ulcers, Stasis" ),

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2  
3 Scientific Eletronic Library Online (SCIELO): ("Unna Boot" OR "Unna's boot" OR  
4 "Unna's paste" OR "Unna paste" OR "Bota de Unna" OR "Bota de Unna") AND (  
5 "Wound Healing" OR "Cicatrización de Heridas" OR Cicatrizaçã) AND ( "Varicose  
6 Ulcer" OR "Úlcera Varicosa" OR "Úlcera Varicosa")  
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