Author (year)
Reference Contact: name and email Funding body of SR

Assessing study relevance: eligibility criteria

What was the aim of the SR?

Did the paper provide a sound rationale for the SR?

How did they define ulcer?

Eligibility criteria in relation to the Overview PICO?	
Participants: patients with diabetes	
Intervention: any complex or simple preventative intervention	
Comparisons: any complex or simple preventative intervention, standard care, or placebo or inert control	
Outcomes: either foot ulcer or amputation	
Did the SR exclude on the basis of language?	

SR eligibility criteria	
Inclusion	**Exclusion**

Does the review question match the question in the overview?

A priori protocol	
SR mentioned in a priori protocol:	
Protocol was published	

Risk of Bias assessment

Describe the study eligibility criteria, any restrictions on eligibility and whether there was evidence that objectives and eligibility criteria were pre-specified: Can best make judgement on this if an a priori study protocol was developed and is available				
1.1 Did the SR adhere to pre-defined objectives and eligibility criteria?		**Y**	**N**	**U**
1.2 Were the eligibility criteria appropriate for our question?		**Y**	**N**	**U**
1.3 Were eligibility criteria unambiguous? No information re the control		**Y**	**N**	**U**
1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)?		**Y**	**N**	**U**
1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or format, language, availability of data)?	**Y**	**N**	**U**	**NA**
Concerns/rationale				
Describe methods of study identification and selection (e.g. number of reviewers involved):				
2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports?		**Y**	**N**	**NR**
2.2 Were methods additional to database searching used to identify relevant reports?		**Y**	**N**	**NR**

2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?	**Y**	**N**	**II**
2.4 Were restrictions based on date, publication format, or language appropriate?	**Y**	**N**	**NR**
2.5 Were efforts made to minimise error in selection of studies?	**Y**	**N**	**NR**
Concerns/rationale			
Describe methods of data collection, what data were extracted from studies or collected through other means, how risk of bias was assessed (e.g. number of reviewers involved) and the tool used to assess risk of bias:			
3.1 Were efforts made to minimise error in data collection?	**Y**	**N**	**U**
3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?	**Y**	**N**	**U**
3.3 Were all relevant study results collected for use in the synthesis?	**Y**	**N**	**U**
3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria? Cochrane Handbook	**Y**	**N**	**U**
3.5 Were efforts made to minimise error in risk of bias assessment? **Y**	**N**	**U**	**NR**
Concerns/rationale			
Describe synthesis methods:			
4.1 Did the synthesis include all studies that it should?	**Y**	**N**	**U**
4.2 Were all pre-defined analyses reported or departures explained?	**Y**	**N**	**NI**
4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies?	**Y**	**N**	**U**
4.7 Did the SR devise a theoretical model of how the interventions work, why and for whom? In rationale	**Y**	**N**	**U**
4.8 Did the SR devise a preliminary synthesis?	**Y**	**N**	**U**
4.9 Did the SR explore relationships in the data?	**Y**	**N**	**U**
4.10 Did the SR assess the robustness of the synthesis product?	**Y**	**N**	**U**
Concerns/rationale			

Y = Yes; N = No; U = Unclear; NA = Not Applicable; NR = Not Reported; II = Insufficient Information; NR = Not Relevant

Concerns regarding specification of study eligibility criteria: Low / Medium / High

Identification and selection of studies included in the SR

What was the search strategy?		
Search strategy:		
Search engine	Start date	End date

Additional searches (e.g. grey literature)

How many RCTs did the SR include?	**N**
1. Reference 2. Reference 3. Etc	
Was a flow diagram reported?	

If reported in the SR, what types of RCTs were included?

How the findings were synthesised

Categorise the method of analysis

Judging risk of bias in the review

Summarize the concerns identified before:	
Domain	Concern and rationale for concern
1. Concerns regarding specification of study eligibility criteria	
2. Concerns regarding methods used to identify and/or select studies	
3. Concerns regarding methods used to collect data and appraise studies	
4. Concerns regarding the synthesis and findings	

How reliable were the conclusions?

What were the conclusions of the SR?
Conclusions/recommendation(s): •
Do the conclusions match the results? •

	Yes	**No**	**Unclear**
Was the search strategy published in the protocol or the review?			
• Dates searched			
• Databases searched			
• Search string and MeSH reported			
Which tool was used for QA? • Amsterdam/Maastricht consensus list (10/5/2) system as initially described by Verhagen et al (1998)			
Is the QA tool a checklist or a scale?	Checklist	Scale	
Has the QA tool been validated or is it an assembled set of items?	Validated	Assembled	
What was the reviewer's judgment about the quality of the studies? •			
Was there an *a priori* plan for the analysis (reported in either the protocol or the methods section of the review)	Yes	No	Unclear
Did the reviewers include studies of different design?	Yes	No	Unclear
List different study designs • •			
Was the evidence from different study designs presented separately in the review?	Yes	No	Not applicable
Were the conclusions based partly on non-RCT evidence?	Yes	No	Not applicable
Did the SR report evidence of effectiveness? *	Yes	No	Unclear
For what interventions?			
• Enhanced patient education and caretaker monitoring			
• Therapeutic footwear and insoles			
• Debridement			
• Achilles tendon lengthening			
• Plantar foot temperature guided avoidance therapy			

Search strategy utilised

- Search string:
- Boolean:
- MeSH:
- Truncation:

Participants

- Total N: participants
    - Males –
    - Females –
- Age: mean (range) –
- Ulcer risk classification:

Intervention

- Casting
- Footwear
- Surgical offloading:
- Other offloading techniques

Control

- Comparison: standard care alone; no intervention; or sham treatment

Outcomes

- Ulcer prevention, ulcer healing, and the reduction of mechanical pressure, i.e. offloading.:

Study results **Categorising the evidence for intervention …**			
Intervention	**Sufficient evidence**	**Some evidence**	**Insufficient evidence**