

CADTH RAPID RESPONSE REPORT:  
SUMMARY WITH CRITICAL APPRAISAL

# Preventative Foot Care for Patients with Diabetes: A Review of Clinical Effectiveness and Cost- Effectiveness

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## Abbreviations

AMSTAR 2	A Measurement Tool to Assess Systematic Reviews 2
CADTH	Canadian Agency of Drugs and Technologies in Health
CRD	University of York Centre for Reviews and Dissemination
IWGDF	International Working Group on the Diabetic Foot
NRS	non-randomized study
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PubMed	Public MEDLINE
RCT	randomized controlled trial
SR	systematic review

## Context and Policy Issues

Diabetes mellitus is a chronic disease that is currently one of the largest global health emergencies.<sup>1</sup> It is estimated that 415 million people across the world are currently living with diabetes.<sup>1</sup> As a nation, Canada has not been immune to this emergency. In 2015, 3.4 million Canadians or 9.3% of the population had diabetes.<sup>1</sup> These numbers are predicted to rise to 5 million or 12.1% by the year 2025.<sup>1</sup>

There are two main classifications of diabetes mellitus: type 1 diabetes and type 2 diabetes.<sup>2</sup> Type 1 diabetes' onset often occurs before the age of 25 years and it is characterized by the destruction of pancreatic beta cells which leads to an insulin deficiency.<sup>2</sup> On the other hand, type 2 diabetes' onset most commonly occurs at an older age, but has been recently increasing in adolescents due to the increasing rate of child and adolescent obesity.<sup>2</sup> Type 2 diabetes is characterized by a combination of increased insulin resistance (i.e., decreased insulin sensitivity) and a relative insulin deficiency.<sup>2</sup> Both main types of diabetes can lead to a variety of chronic conditions including microvascular and macrovascular complications.<sup>2</sup>

A major cause of morbidity and mortality amongst patients with diabetes is foot complications such as foot ulcers and infections which can lead to lower limb amputations.<sup>3</sup> In Canada, adult patients with diabetes are 20 times more likely to be hospitalized for a lower limb amputation compared to adults without diabetes.<sup>3</sup> Risk factors for developing foot ulcers include microvascular complications (especially peripheral neuropathy), peripheral arterial disease, structural foot deformity, and a previous foot ulcer.<sup>3</sup> Once a foot ulcer has developed, treatment usually involves an interprofessional healthcare team and consists of a combination of wound care, infection control, off-loading of high pressure areas of the foot, checking lower-extremity vascular status, and glycemic control.<sup>3</sup> A preventative foot care routine may reduce the development of foot ulcers.<sup>3</sup> Preventative foot care routines involve a variety of interventions such as foot inspection, basic care, education and information on foot care. However, there is very little research on the clinical effectiveness or cost-effectiveness of these interventions in asymptomatic feet.<sup>4</sup>

Numerous CADTH reports have addressed diabetic foot ulcer prevention,<sup>4</sup> screening,<sup>5</sup> and treatment.<sup>6</sup> A CADTH report published in 2018 reviewed the evidence regarding preventative foot care for patients with diabetes and found one systematic review which suggested that the implementation of a health education program improved foot self-care scores and foot problems.<sup>4</sup> This report will update components of the previous CADTH report<sup>4</sup> related to the clinical effectiveness and cost-effectiveness of preventative foot care for patients with diabetes and asymptomatic feet.

## Research Questions

1. What is the clinical effectiveness of providing preventative foot care for patients with diabetes and asymptomatic feet?
2. What is the cost-effectiveness of providing preventative foot care for patients with diabetes and asymptomatic feet?

## Key Findings

One relevant systematic review of critically low-quality was identified regarding the clinical effectiveness of providing preventative foot care for patients with diabetes and asymptomatic feet. The systematic review included two relevant primary studies; one of which found motivational interviewing had no effect on the incidence of ulceration and the other which found motivational coaching along with self-management education and diabetes care monitoring decreased foot risk and amputations at one year. Overall, the systematic review suggested that there is insufficient evidence on the effectiveness of motivational interviewing to enhance adherence to behaviors to prevent diabetic foot ulceration compared to control. No evidence regarding the cost-effectiveness of providing preventative foot care for patients with diabetes and asymptomatic feet was identified.

## Methods

### Literature Search Methods

The literature search for this report was an update of a literature search strategy developed for a previous CADTH report.<sup>4</sup> For the current report, a limited literature search was conducted on key resources including PubMed, the Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. The initial search was limited to English-language documents published between January 1, 2008 and October 17, 2018. For the current report, database searches were rerun on October 23, 2019 to capture any articles published since the initial search date. The search of major health technology agencies was also updated to include documents published since October 2018.

### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

**Table 1: Selection Criteria**

<b>Population</b>	Patients with diabetes and asymptomatic feet Potential subgroups of interest: uninsured patients
<b>Intervention</b>	Preventative foot care (e.g., foot inspection, basic care, education and information on foot care, risk stratification for ulceration)
<b>Comparator</b>	No treatment specific to feet
<b>Outcomes</b>	Q1: Clinical effectiveness (e.g., prevention of ulcers, foot disease [e.g., Charcot foot, osteomyelitis, infection], and amputations) Q2: Cost-effectiveness
<b>Study Designs</b>	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic evaluations

### Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to October 2018.

### Critical Appraisal of Individual Studies

The included systematic review<sup>7</sup> (SR) was critically appraised by one reviewer using the AMSTAR 2 tool.<sup>8</sup> Summary scores were not calculated for the included study; rather, a review of the strengths and limitations of the included study was described narratively.

## Summary of Evidence

### Quantity of Research Available

A total of 103 citations were identified in the literature search. Following screening of titles and abstracts, 99 citations were excluded and four potentially relevant reports from the electronic search were retrieved for full-text review. One potentially relevant publication was retrieved from the grey literature search for full-text review. Of these potentially relevant articles, four publications were excluded for various reasons, and one publication, a SR,<sup>7</sup> met the inclusion criteria and was included in this report. Appendix 1 represents the PRISMA<sup>9</sup> flowchart of the study selection. Additional citations that did not meet the inclusion criteria but may be of interest are included in Appendix 5.

### Summary of Study Characteristics

One relevant SR was identified and included in this report.<sup>7</sup> No relevant health technology assessments, meta-analyses, randomized controlled trials, non-randomized studies, or economic evaluations were identified. Detailed characteristics are available in Appendix 2.

### *Study Design*

One SR with a narrative synthesis published in 2019 was included.<sup>7</sup> Multiple databases were searched from inception to November 2017 with no language restrictions.<sup>7</sup> The scope of the SR was broader than the inclusion criteria of this report as it also included patients with current diabetic foot ulcers and looked at behavioral as well as ulceration outcomes.<sup>7</sup> As such, two of the five studies included in the SR (one randomized controlled trial

published in 2011 and one non-randomized study published in 2002) were relevant to this report.<sup>7</sup>

#### *Country of Origin*

The authors of the SR were based in the United Kingdom and the Netherlands.<sup>7</sup> It was not reported where the relevant primary studies were conducted.

#### *Patient Population*

Studies were included in the SR if the participants were 18 years or older, had any type of diabetes, and were at risk of developing diabetic foot ulceration.<sup>7</sup> In the SR, the relevant randomized controlled trial (RCT) was conducted at an undescribed specialist center and enrolled patients with type 1 or type 2 diabetes with a previous ulceration that was healed.<sup>7</sup> The other relevant primary study in the SR, a non-randomized study (NRS), was conducted at a dialysis unit and enrolled patients with type 1 or type 2 diabetes with end stage renal disease.<sup>7</sup>

#### *Interventions and Comparators*

Studies were included in the SR if they used motivational interviewing or a motivational approach to improve adherence to behaviors for the prevention of diabetic foot ulceration.<sup>7</sup> Motivational interviewing or a motivational approach were either the sole intervention or part of the intervention.<sup>7</sup> The intervention in the RCT included in the SR was participant driven, enquiry-led questions aimed to build self-confidence.<sup>7</sup> This was a group-based intervention delivered in a one time, 60-minute session with a follow-up period of six months.<sup>7</sup> The intervention in the NRS included in the SR was motivational coaching along with self-management education and diabetes care monitoring.<sup>7</sup> This was a one-to-one intervention delivered two to three times weekly to patients with diabetes who were undergoing hemodialysis and once a month to patients undergoing peritoneal dialysis.<sup>7</sup> With patients undergoing both types of dialysis, the delivery of the intervention continued for an unspecified length of time; however, the follow-up period was one year.<sup>7</sup>

Details of the comparator groups for the RCT and NRS included in the SR were not discussed. However, the authors of the SR stated they accepted all types of controls including no comparator as long as the study was prospective with a before and after design.<sup>7</sup>

#### *Outcomes*

The outcomes in the SR which were of interest for this report were the incidence of ulceration reported in the included RCT and amputations after one year reported in the NRS.<sup>7</sup> Furthermore, another potential outcome of interest reported in the included NRS was “foot risk”, however, no definition of this outcome was provided.<sup>7</sup>

#### **Summary of Critical Appraisal**

The SR by Binning et al.<sup>7</sup> had several strengths. The objective of the review as well as the eligible interventions, comparators and outcomes components were clearly stated.<sup>7</sup> A comprehensive literature search was performed without date or language restrictions, search strategies for each database were reported and appropriate, and study selection was completed in duplicate.<sup>7</sup> The authors described the heterogeneity across included studies and the decision not to conduct a meta-analysis was justified.<sup>7</sup> The risk of bias of the included studies was assessed using a 21-point checklist that assessed relevant criteria

such as study design, study conduct, and outcomes.<sup>7</sup> The authors also considered the risk of bias of individual studies when interpreting and discussing results.<sup>7</sup>

However, the SR was graded to be of critically low-quality because of the numerous weaknesses identified. The characteristics of included participants were poorly described. Specifically, studies were eligible for inclusion if the patients were “at risk” of diabetic foot ulceration, however the International Working Group on the Diabetic Foot<sup>10</sup> (IWDF) risk classification was used without specifying which of the four categories of risk were included.<sup>7</sup> An *a priori* protocol was not reported for the review and neither a list of excluded studies nor the reasons for exclusion were provided. This decreases confidence in the review as it was unclear which publications may have been omitted. The studies included in the systematic review were poorly described and no numerical data nor any statistical comparisons from the studies were provided in the review; rather, the studies’ conclusions were described narratively. Data extraction was not done in duplicate, and it was unclear if the study characteristics and results were poorly reported by the original authors or by the authors of the SR.<sup>7</sup> The authors disclosed that they had no conflicts of interest related to this review,<sup>7</sup> however, the funding sources of the primary studies and of the systematic review were not reported, thus the potential impact of funding organizations was unclear. Additional details regarding the strengths and limitations of the included systematic review are included in Appendix 3.

## Summary of Findings

One SR with two studies relevant to this report was identified.<sup>7</sup> Appendix 4 presents a table of the main study findings and the authors’ conclusions.

### *Clinical Effectiveness of Preventative Foot Care for Patients with Diabetes*

#### **Incidence of Ulceration**

Evidence from the RCT included in the SR found that group based, participant driven, enquiry-led questions did not improve foot ulceration rates compared with an unspecified control.<sup>7</sup> The authors of the SR assessed the RCT to have a high risk of bias.<sup>7</sup>

#### **Amputations After One Year**

Evidence from one NRS included in the SR found that motivational coaching combined with self-management education and diabetes care monitoring was effective at improving amputations after one year compared to an unspecified control.<sup>7</sup> The authors of the SR assessed the NRS to have a high risk of bias.<sup>7</sup>

#### **Foot Risk**

Evidence from the same NRS included in the SR also found that motivational coaching combined with self-management education and diabetes care monitoring was effective at improving foot risk compared to an unspecified control.<sup>7</sup>

### *Cost-Effectiveness of Preventative Foot Care for Patients with Diabetes*

No relevant cost-effectiveness studies regarding preventative foot care for patients with diabetes were identified; therefore, no summary can be provided.

## Limitations

There were numerous limitations to this review, one of which was the small amount of literature identified. Studies not meeting the inclusion criteria of this report often compared one preventative foot care method to another rather than to no treatment specific to feet. Furthermore, the included SR identified one relevant RCT (N= 131) and one relevant NRS (N= 83) which were assigned a high risk of bias according to the authors' assessment.<sup>7</sup> These two primary studies represent evidence for specific interventions. As such, no evidence for other types of preventive foot care such as foot inspection, basic care or risk stratification for ulceration was found. This report was also limited by the uncertainty regarding the population of the included SR. The authors of the SR did not provide a specific definition for patients at risk of foot ulceration. Rather, they classified patients as "at risk" using the IWDGF<sup>10</sup> risk classification system and did not specify which categories of the system they included in their population.<sup>7</sup> This lack of definition along with the poor description of the included primary studies resulted in an unclear population, and it was uncertain whether all patients met the population criteria specified in this report. The generalizability of the SR to the population of interest is thus unclear. The SR also did not include where the primary studies were conducted. Thus, it is unknown whether the findings are generalizable to the Canadian setting. Lastly, there was no evidence on the cost-effectiveness of preventative foot care for patients with diabetes. This suggests that additional research is required.

## Conclusions and Implications for Decision or Policy Making

One SR of critically low-quality was identified regarding the clinical effectiveness of providing preventative foot care for patients with diabetes and asymptomatic feet.<sup>7</sup> No evidence regarding the cost-effectiveness of providing preventative foot care for patients with diabetes and asymptomatic feet was identified.

The included SR contained one relevant RCT and one relevant NRS which were both assessed to have a high risk of bias by the authors.<sup>7</sup> The relevant RCT found that group based, participant driven, enquiry-led questions did not improve foot ulceration rates compared to an unspecified control. The relevant NRS found that motivational coaching as an intervention combined with self-management education and diabetes care monitoring was effective at improving foot risk and amputations after one year compared to an unspecified control. Given the small quantity of low-quality, heterogenous evidence, and the limitations identified in this report, there was insufficient evidence for the effectiveness of motivational interviewing for decreasing diabetic foot ulcerations.

The previous CADTH report similarly found very little evidence regarding the clinical effectiveness of providing preventative foot care for patients with diabetes and asymptomatic feet.<sup>4</sup> The SR included in the previous CADTH report was also of critically low-quality but findings suggested that health education programs improved foot self-care and foot problems (such as neuropathy, foot disability, lesion, ulcer, tinea pedis and callus grade) compared to usual care, written education or unspecified controls.<sup>4</sup> The difference in conclusions between the SR included in the previous report and the SR of this report can be attributed to the different interventions assessed.<sup>4,7</sup>

Preventative foot care for patients with diabetes involves a variety of interventions including foot inspection, basic foot care, education and information on foot care, and risk stratification for ulceration. The lack of evidence in this report as well as the previous report

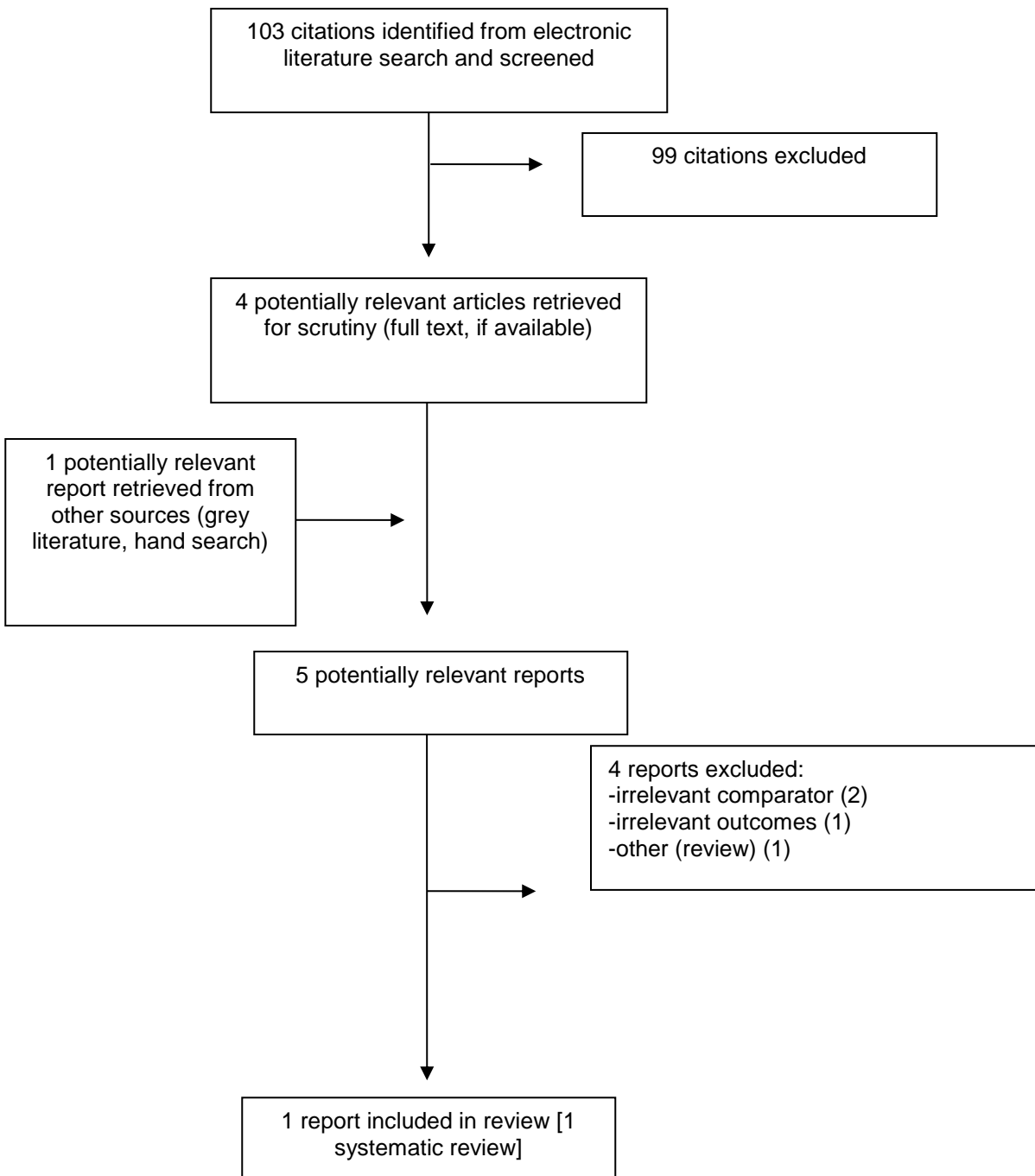


suggests the need for well-designed RCTs to investigate the clinical effectiveness of various interventions for preventative foot care in patients with diabetes.

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## Appendix 1: Selection of Included Studies



## Appendix 2: Characteristics of Included Publications

**Table 2: Characteristics of Included Systematic Review**

First Author, Publication Year, Country, Funding	Study Design, Search Strategy, Numbers of Studies Included, Quality Assessment Tool, and Objective	Population Characteristics	Intervention and Comparators	Clinical Outcomes, Length of Follow-Up
<p><b>Binning, 2019<sup>7</sup></b></p> <p><b>Countries:</b> United Kingdom, Netherlands</p> <p><b>Funding:</b> Not disclosed</p>	<p><b>Study design:</b> SR of peer reviewed articles.</p> <p><b>Literature search strategy:</b> Authors performed literature searches in MEDLINE, CINAHL, ProQuest (Health and Medical Collection, Nursing and Allied Health Database, PsycINFO, Psychology, PsychArticles), AMED, EMBASE, The Cochrane Central Register of Controlled Trials, ScienceDirect, and Web of Science Core Collections up to November 2017. These searches were supplemented by a snowballing of reference lists and a grey literature search. There was no date or language restrictions, but searches were limited to adults.</p> <p><b>Number of studies included:</b> Five studies were included in the SR; two of these were relevant studies (one RCT and NRS).</p> <p><b>Quality assessment tool:</b> Conducted using an unnamed assessment tool comprised of a 21-point checklist.</p>	<p>Adults patients with any type of diabetes, classified as at risk of developing diabetic foot ulceration (as per the IWDGF<sup>10</sup>). Patients with risk factors for ulceration or current/ recurrent ulceration were also included.</p> <p>The relevant RCT included patients with type 1 or type 2 diabetes and a previous ulcer which has now healed (N=131) and the relevant NRS included patients with type 1 or type 2 diabetes with end stage renal disease (N=83).</p>	<p><b>Interventions:</b> Motivational interviewing or a motivational approach as the sole intervention or as part of the intervention.</p> <p><b>Comparators:</b> All types of controls including studies without comparators as long as they were prospective with a before and after design.</p> <p>The intervention in the relevant RCT was enquiry-led questions aimed to build self-confidence; the intervention in the relevant NRS was motivational coaching, self-management education and diabetes care monitoring. Neither study had its control described.</p>	<p><b>Relevant Outcomes:</b></p> <ul style="list-style-type: none"> <li>- Incidence of ulceration</li> <li>- Amputations (details not provided)</li> <li>- Foot risk (not defined in the SR)</li> </ul> <p><b>Follow-up:</b> minimum of 6 months</p>

**Table 2: Characteristics of Included Systematic Review**

First Author, Publication Year, Country, Funding	Study Design, Search Strategy, Numbers of Studies Included, Quality Assessment Tool, and Objective	Population Characteristics	Intervention and Comparators	Clinical Outcomes, Length of Follow-Up
	<p><b>Objective:</b> To determine if motivational interviewing was effective in improving adherence behaviors for the prevention of diabetic foot ulceration.</p>			

AMED = Allied and Complementary Medicine Database; CINAHL = Cumulative Index to Nursing and Allied Health Literature; EMBASE = Excerpta Medica database; IWDGF = International Working Group on the Diabetic Foot; MEDLINE = Medical Literature Analysis and Retrieval System Online; NRS = non-randomized study; PsycINFO = Psychological Information database; RCT = randomized controlled trial; SR = systematic review.

## Appendix 3: Critical Appraisal of Included Publications

**Table 3: Strengths and Limitations of Systematic Review using AMSTAR 2<sup>8</sup>**

Strengths	Limitations
Binning et al., 2019 <sup>7</sup>	
<ul style="list-style-type: none"> <li>• The objective of the review was clearly stated</li> <li>• The eligible interventions, comparators and outcomes of the review were well defined</li> <li>• A comprehensive literature search of multiple databases, the snowballing of reference lists and a grey literature search was performed</li> <li>• Literature search was performed without date or language restrictions</li> <li>• Thorough search strategies of the databases were used and described in detail</li> <li>• Study selection was completed in duplicate and described in detail</li> <li>• A list of included studies was provided</li> <li>• Authors considered risk of bias in individual studies when interpreting and discussing results</li> <li>• Authors described heterogeneity across studies and the reason for not conducting a meta-analysis of results</li> <li>• Authors disclosed that they had no conflicts of interest related to this review</li> </ul>	<ul style="list-style-type: none"> <li>• The eligible population of the review was poorly described and inclusion criteria poorly defined</li> <li>• An <i>a priori</i> protocol was not reported for the review</li> <li>• Data extraction from included studies was not done in duplicate</li> <li>• Study findings were reported narratively with no numerical data or statistical comparisons provided</li> <li>• Neither a list of excluded studies nor the reasons for exclusion were provided</li> <li>• The included studies' characteristics were poorly described</li> <li>• Funding sources of included studies not provided</li> <li>• Funding sources of review not disclosed</li> </ul>

## Appendix 4: Main Study Findings and Authors' Conclusions

**Table 4: Summary of Findings of Included Systematic Review**

Main Study Findings	Authors' Conclusion
Binning et al., 2019 <sup>7</sup>	
<p><b>Incidence of ulceration:</b> One RCT (high risk of bias) reported that the intervention did not improve ulceration rates compared with the control group (data and statistical comparisons not provided)</p> <p><b>Foot risk and incidence of amputation:</b> One NRS (high risk of bias) reported that the intervention was effective at improving foot risk and amputations after one year (data and statistical comparisons not provided)</p>	<p><i>“There is insufficient evidence on whether motivational interviewing or aligned behavioral interventions are effective at enhancing adherence in order to prevent diabetic foot ulceration.” (p. 8)</i></p>

## Appendix 5: Additional References of Potential Interest

### Systematic Review of Guidelines

Perez-Panero AJ, Ruiz-Munoz M, Cuesta-Vargas AI, Gonzalez-Sanchez M. Prevention, assessment, diagnosis and management of diabetic foot based on clinical practice guidelines: A systematic review. *Medicine*. 2019 Aug;98(35):e16877.

[PubMed: PM31464916](#)

### Randomized Controlled Trials- Different Comparators

Effectiveness of a Self-Foot-Care Educational Program for Prevention of Diabetic Foot Disease. *Health*. 2019;11(1).

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