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FOOT ULCER PREVENTION IN PEOPLE WITH DIABETES MELLITUS

PREVENÇÃO DA ÚLCERA DO PÉ NA PESSOA COM DIABETES MELLITUS

PREVENCIÓN DE ÚLCERA DEL PIE EN PERSONAS CON DIABETES MELLITUS

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ABSTRACT

Objective: Identify strategies for foot ulcer prevention in people with diabetes *Mellitus*.

Methods: Integrative literature review based on studies published in the last five years (2014-2019) selected from the search engines EBSCO and PubMed/MedLine, with the keywords foot ulcer, diabetes *Mellitus*, nursing care, prevention, and control.

Results: 7 articles were selected to be part of the integrative literature review. Their analysis showed three categories of strategies for the prevention of foot ulcer in people with diabetes *Mellitus*: integrated foot care, self-management interventions and therapeutic footwear.

Conclusion: There is strong evidence to support the use of strategies for preventing foot ulcer recurrence, such as monitoring the skin temperature of the feet and consequent preventive actions, and the consistent use of therapeutic footwear. Quality and controlled studies are needed especially in the areas of integrated foot care and self-management interventions.

Keywords: Diabetes Mellitus; Foot Ulcer; Nursing Care; Prevention.

RESUMO

Objetivo: Identificar as estratégias para a prevenção da úlcera do pé na pessoa com Diabetes *Mellitus*.

Métodos: Revisão integrativa da literatura com base nos estudos publicados nos últimos cinco anos (2014-2019) selecionados dos motores de busca EBSCO e PubMed/MedLine, com os descritores úlcera do pé, diabetes *Mellitus*, cuidados de enfermagem, prevenção e controlo.

Resultados: Selecionaram-se 7 artigos para integrarem a revisão integrativa da literatura. Da sua análise evidenciaram-se três categorias de estratégias para a prevenção da úlcera do pé na pessoa com diabetes *Mellitus*: cuidados integrados ao pé, intervenções de autogestão e calçado terapêutico.

Conclusões: Existe evidência forte que suporta a utilização de estratégias para a prevenção da reincidência da úlcera do pé, nomeadamente a monitorização da temperatura da pele dos pés e consequentes ações preventivas, e a utilização consistente de calçado terapêutico. Estudos controlados e de qualidade são necessários sobretudo nas áreas dos cuidados integrados do pé e das intervenções de autogestão.

Palavras-chave: Cuidados de Enfermagem; Diabetes Mellitus; Prevenção; Úlcera do Pé.

RESUMEN

Objetivo: Identificar estrategias para la prevención de la úlcera del pie en personas con diabetes *Mellitus*.

Métodos: Revisión integral de la literatura basada en estudios publicados en los últimos cinco años (2014-2019) seleccionados de los motores de búsqueda EBSCO y PubMed/MedLine, con los descriptores úlcera del pie, diabetes *Mellitus*, atención de enfermería, prevención y control.

Resultados: Fueram seleccionados 7 artículos para ser parte de la revisión integral de la literatura. A partir de su análisis, tres categorías de estrategias para la prevención de la úlcera del pie en la persona con diabetes *Mellitus*: cuidado integral del pie, intervenciones de autogestión y calzado terapéutico.

Conclusiones: Existen pruebas sólidas para apoyar el uso de estrategias para prevenir la recurrencia de la úlcera del pie, como el control de la temperatura de la piel de los pies y las acciones preventivas consiguientes, y el uso constante de calzado terapéutico. Se necesitan estudios de calidad y controlados, especialmente en las áreas de cuidados integrados del pie y las intervenciones de autogestión.

Descriptores: Atención de Enfermería; Diabetes Mellitus; Prevención; Úlcera del Pie.

INTRODUCTION

The incidence of diabetes Mellitus is growing at an overwhelming pace worldwide. In 2016, around 400 million people worldwide were living with diabetes Mellitus[1], and it is estimated that this number will rise to 642 million by 2040[2]. In Portugal, the prevalence of diabetes Mellitus is situated at 9.8% in the population between 25 and 74 years old and at 23.8% between 65 and 74 years old[3]. In 2015, diabetes Mellitus accounted for 12% of global health expenditures[4]. However, the weight of expenditure on diabetes Mellitus goes beyond direct medical costs, adding the indirect costs associated with lost productivity, premature mortality and the negative impact on the gross domestic product of each nation[1].

A foot ulcer is one of the most serious complications in people with diabetes Mellitus[5]. The International Working Group on the Diabetic Foot[6] defines a foot ulcer as a break in the skin of the foot that includes at least the epidermis and part of the dermis. Foot ulceration occurs in up to 25% of people with diabetes Mellitus throughout their lives, more than half of all foot ulcers will become infected and 20% of these infections will progress to amputation[4].

In this regard, the National Diabetes Program[7] emphasizes that most amputations can be prevented if foot ulcer complications are treated in advance. Changing the focus from the treatment of diabetic foot ulcers to prevention is, therefore, essential[4]. The study of strategies for the prevention of foot ulcers in people with diabetes Mellitus becomes preponderant for the provision of quality care based on the most current evidence.

METHODS

The integrative literature review allows access to current scientific knowledge, by analyzing and synthesizing the evidence produced on the problem under study, allowing a critical evaluation and, therefore, discovering possible research opportunities[8]. A research question was formulated to guide the investigation: What are the effective strategies in preventing foot ulcers in people with diabetes Mellitus, compared to the absence of intervention or other prevention strategies, in health care settings or in the community?

The research question was constructed according to the PICOD methodology (Participants/Population, Intervention, Comparison, Outcomes, Study design), seeking to identify strategies for the prevention of foot ulcers in people with diabetes Mellitus.

After formulating the research question, the inclusion criteria were outlined for the selection of studies to be analyzed:

- Population – Adults with type 1 or type 2 diabetes Mellitus;
- Phenomenon of interest – Prevention of foot ulcer, first or recurrent;
- Outcomes – Strategies for foot ulcer prevention;
- Design – Quantitative, qualitative and mixed studies, excluding case studies, published between January 1, 2014 and July 31, 2019, in Portuguese, English or Spanish, and freely available in full text.

The following exclusion criteria were defined: articles related to studies with bedridden individuals or with Charcot's neuroarthropathy, due to their unique characteristics that increase the risk of ulcers and require differentiated care; articles that focused exclusively on educational strategies; articles whose results were related to surgical interventions, since this is an exclusively medical activity; articles with unspecified methodology; and articles from study or institutional protocols.

On August 5, 2019, a survey was carried out using the search engines EBSCO and PubMed/MedLine, using descriptors and qualifiers identified on the platform "Descriptors in Health Sciences"[9].

The following combinations of search terms were used in both search engines: "foot ulcer" AND "diabetes Mellitus" AND "nursing care"; "foot ulcer" AND "diabetes Mellitus" AND "prevention & control"; "foot ulcer" AND "diabetes Mellitus" AND "nursing care prevention & control".

Initially, the titles and keywords of the publications resulting from the research were analyzed to identify those that fit the objectives of this integrative review and exclude duplicates. Then, the abstracts were read to organize the pre-selected studies according to the defined criteria. Subsequently, the pre-selected articles were read in full, and the previously defined inclusion and exclusion criteria were applied, resulting in the selection of 7 publications for the elaboration of the integrative review. This process is depicted in Figure 1↗.

RESULTS

The methodological quality and level of evidence of the selected studies were assessed based on the Joanna Briggs Institute (JBI) method for quantitative and qualitative studies[11]. To systematize the presentation of the results of the studies and their evaluation and enhance their understanding, Chart 1↗ was produced.

DISCUSSION

The analysis of the results obtained identified three categories of foot ulcer prevention strategies in people with diabetes Mellitus: integrated foot care, self-management interventions and therapeutic footwear.

Integrated foot care

Integrated foot care was defined as care provided on more than one occasion by a health professional or multidisciplinary team, combining two or more foot ulcer prevention strategies in people with diabetes Mellitus[12,14]. Although these precautions are common in clinical practice around the world, few high-quality studies have addressed this issue[12]. Of the seven articles analyzed, two systematic reviews of the literature refer to this category.

Foot ulcer prevention strategies, the place where care is provided, the time between treatments and the characteristics of people with diabetes Mellitus were different between studies[12,14], which makes it difficult, and in some cases impossible, to compare them. However, Netten *et al*[14] describe that, despite the care had been different between studies, they always included the removal of calluses, nail trimming, patient education, prescription of therapeutic footwear and advice on the use of footwear. However, details were lacking in all studies so that the programs could be reproduced[14].

The risk of ulceration seems to be lower in people with diabetes Mellitus who adhere to integrated foot care programs[14]. Due to the low quality of the studies, the findings by Netten *et al*[14] are not likely to draw relevant conclusions regarding the prevention of a first foot ulcer. Hoogeveen *et al*[12] came across two randomized controlled studies that reported that integrated foot care decreased the occurrence of amputation and foot ulcer recurrence, but the studies had an unclear or high risk of bias.

Consequently, there is not enough evidence to support the use of integrated foot care[12]. Having little evidence is not the same as saying that integrated foot care is not effective. Netten *et al*[14] point out that this type of care can effectively prevent the recurrence of foot ulcers in people with diabetes Mellitus. Therefore, it seems advisable to focus the efforts of professionals and health units on people with diabetes Mellitus at high risk of ulceration after a clinical evaluation[12]. Studies with better methodological quality and likely to be reproduced and comparable are needed.

Self-management interventions

Self-management, through daily observation and evaluation of the feet, as a foot ulcer prevention method is essential, allowing the early identification of any abnormality[14]. One of the greatest difficulties observed in clinical practice is the adherence of people with diabetes Mellitus to daily foot care.

Netten *et al*[14] concluded, through a systematic review they authored, that the use of antifungal varnish as a method to increase the frequency of daily foot assessment is not supported by the literature. People with diabetes Mellitus who are prescribed an antifungal varnish do not observe their feet more often than those who are not prescribed this treatment[14].

In turn, monitoring the skin temperature of the feet proved to be a viable alternative, not only in daily compliance, but also in the prevention of foot ulcer recurrence[14,17]. The asymmetry of skin temperature on the sole at 6 points during two consecutive days, when compared with the contralateral foot, seems to predict future ulcerations[17]. This intervention

instantly provides clinically relevant information[14], which may be a factor in increasing daily adherence.

In the study by Skafjeld *et al*[17] a digital infrared thermometer was used by people with diabetes Mellitus with a previous history of ulcers and diagnosed neuropathy (high risk of ulceration), at home. The authors[17] considered a temperature asymmetry greater than 2.0°C, however, they do not refer to the six points evaluated, so it is not possible to replicate the study. The person with diabetes Mellitus confronted with asymmetries in the skin temperatures of the feet identified by themselves at home for two consecutive days, by contacting health professionals and following their instructions, have the possibility of preventing foot ulcers[14]. However, the study by Skafjeld *et al*[17] did not find significant differences between the control group, which did not assess the skin temperature of the feet, and the intervention group, which performed this assessment, possibly due to the small sample size.

Foot skin temperature monitoring as an intervention to prevent foot ulcers in people with diabetes Mellitus has positive and promising results. Cost-benefit and feasibility studies of its application in the Portuguese population are necessary since this intervention is not implemented as standard in foot care in Portugal.

Therapeutic footwear

Inappropriate footwear used by people with diabetes Mellitus is an external factor for foot ulceration. Thus, of the 7 articles analyzed, 5 of them refer to the use of therapeutic footwear by people with diabetes Mellitus as a foot ulcer prevention strategy.

The findings by Premkumar *et al*[16] corroborate the greater tendency for the development of foot ulcers in people who use inappropriate footwear. López-Moral *et al*[13] refer that the risk of developing a foot ulcer is related to the biomechanics of the foot itself, so the assessment of the risk of developing a foot ulcer allows selecting the most appropriate type of therapeutic footwear for individual characteristics of the person. As postulated[14], footwear prescribed by a health professional, based on an algorithm based on current evidence or on a current guideline, is better than one that is not subject to prescription.

Few studies focus on the prevention of the first foot ulcer in people with diabetes Mellitus through the use of therapeutic footwear[14], which is why investment in the area is suggested for the personal benefits and for the health system that may result therefrom. Preece *et al*[15] addressed this issue from the perspective that an optimized prefabricated shoe model would reduce plantar pressure below 200 kPa in people with diabetes Mellitus with high plantar pressure and low risk of ulceration, without the need for a customized shoe based on plantar pressure. The authors[15] propose a shoe model with a rigid "rocker" sole with an

angle of 20°, incorporating an apex position at 52% of the length. This shoe model reduced the peak plantar pressure to less than 200 KPa in approximately 71-81% of the individuals studied[15]; however, it was not compared with a custom shoe model.

The findings by Preece *et al*[15] suggest that people with diabetes Mellitus with high plantar pressure and low risk of ulceration could only obtain marginal gains with customized footwear based on the assessment of plantar pressure. In comparison, Ulbrecht *et al*[18] conclude that people with diabetes Mellitus at a high risk of plantar ulceration of the metatarsal heads benefit from individually designed and manufactured orthoses, based on the assessment of plantar pressure and the shape of the foot, then medically approved prefabricated.

Based on these promising results, it could be concluded that the prescription of prefabricated orthoses/shoes would be an adequate hypothesis for people with diabetes Mellitus with a low risk of ulceration[15], and the prescription of customized orthoses/shoes based on pressure plantar, and biomechanics of the foot would be essential for those at high risk of ulceration[18]. Studies of good methodological quality are needed so that this hypothesis can be concluded with a high degree of certainty. Nevertheless, the evaluation of plantar pressure favors the effectiveness of the prescribed therapeutic footwear, when compared with the prescription based on the shape of the foot and clinical opinion[14,15,18].

Another aspect highlighted in this category was the characteristics of the soles of shoes suitable for people with diabetes Mellitus. The use of a rigid "rocker" sole for foot ulcer prevention is an applicable strategy for preventing the first foot ulcer in people with high plantar pressure but low risk of ulceration[15], and for preventing foot ulcer recurrence. in people with a history of plantar ulcers of the metatarsal heads, in those with foot deformities and in those who underwent minor amputation[13]. Premkumar *et al*[16] also refer to the need for a hard outer sole, given that the second most common cause of foot ulcers caused by inappropriate footwear in their patients was the penetration of sharp objects through a soft outer sole, causing foreign objects injuries in feet with neuropathy. These authors[16] add the need for a soft inner sole, the existence of a midsole and adjustable front and rear cleats.

CONCLUSIONS

The increasing incidence and prevalence of diabetes Mellitus brings with it the personal and socioeconomic burden of foot ulcers. Therefore, it is worthwhile for health professionals to focus their efforts on preventing its occurrence.

The integrative literature review reveals that there is little evidence to support the use of strategies to prevent initial foot ulcers in people with diabetes Mellitus. However, in contrast, there is robust evidence supporting the use of strategies for the prevention of foot ulcer recurrence. This includes monitoring the skin temperature of the feet and subsequent preventive actions, as well as the consistent use of therapeutic footwear.

In the future, research projects must be carried out to fill the existing gaps. High-quality controlled studies are needed in the area of foot ulcer prevention strategies in people with diabetes Mellitus, especially concerning integrated foot care and self-management interventions. In addition, greater homogeneity in the characteristics of the studies would allow a rigorous analysis and facilitate future comparisons of results. This, in turn, would make it possible to optimize care for people with diabetes Mellitus.

By overcoming these challenges and implementing future research projects, it will be possible to improve foot ulcer prevention care for people with diabetes Mellitus. This would benefit both health professionals in designing effective programs and people with diabetes Mellitus themselves, ensuring better results and a higher quality of life.

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AG: Study coordination, study design, data collection, storage and analysis, review and discussion of results.
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PC: Study design, data analysis, review and discussion of results.
AC: Study design, data analysis, review and discussion of results.
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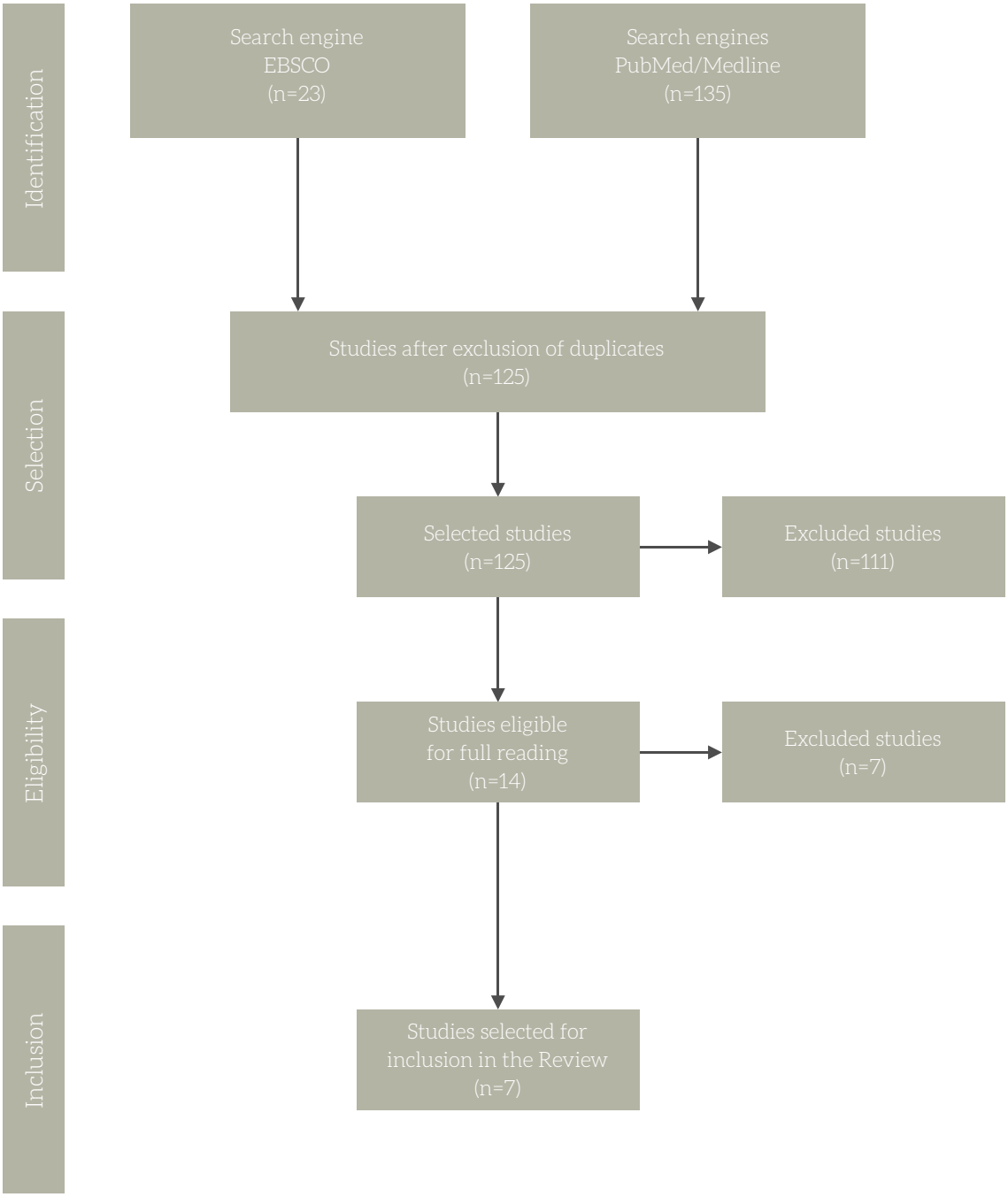

Figure 1 – Study selection flowchart[10].

Chart 1 – Methodological characteristics and main results of the selected studies.

Authors	Study aim	Design/Evidence Level/ Degree of Recommendation	Participants	Phenomenon of interest
Hoogeveen *et al* (2015)[12].	To analyze the effectiveness of complex interventions in preventing foot ulcers in people with diabetes Mellitus, defined as an integrated approach combining two or more prevention strategies, compared with the effectiveness of individual strategies, usual care or alternative complex interventions.	Systematic review of randomized controlled trials 1.a B	Adults with type 1 or type 2 diabetes Mellitus in any health facility, across the 6 studies included in the review.	Complex interventions in the prevention of foot ulcers in people with diabetes Mellitus.
Results/Conclusions	There is insufficient evidence that complex interventions are more effective in preventing or reducing foot ulcers in people with diabetes Mellitus. After clinical selection, it is advisable to concentrate efforts on users with a high risk of ulceration.			
López-Moral (2019)[13].	To evaluate the effectiveness of a rigid "rocker" sole in reducing the recurrence of plantar ulcers in people with diabetes Mellitus.	Controlled experimental study 1.c A	51 users with diabetic neuropathy with a recently healed plantar ulcer.	Use of therapeutic footwear to prevent the recurrence of foot ulcers in people with diabetes Mellitus.
Results/Conclusions	The use of a rigid "rocker" sole is more effective than a semi-rigid "rocker" sole in reducing the recurrence of foot ulcers in people with diabetes Mellitus, in those with a history of plantar ulcers, with foot deformity and/or who have been targeted. of minor amputation.			
Netten *et al* (2016)[14].	To investigate the effectiveness of early and recurrent foot ulcer prevention interventions in people with diabetes Mellitus at risk for ulceration.	Systematic review of controlled and uncontrolled studies 1.b A	People with type 1 or type 2 diabetes Mellitus are at risk of foot ulceration across the 74 studies included in the review.	Interventions in the prevention of foot ulcers in people with diabetes Mellitus.
Results/Conclusions	Foot temperature monitoring at home with subsequent preventive actions and the use of therapeutic footwear consistently worn by the person prevents the recurrence of foot ulcers. Integrated foot care can be effective in preventing foot ulcer recurrence. There is insufficient evidence to support intervention for the prevention of initial foot ulcers in people with diabetes Mellitus at high risk of ulceration, nor for surgical intervention to prevent foot ulcer recurrence. A single education session aimed at preventing foot ulcer recurrence is not supported by the evidence.			

Chart 1 – Methodological characteristics and main results of the selected studies.↔↖

Authors	Study aim	Design/Evidence Level/ Degree of Recommendation	Participants	Phenomenon of interest
Preece *et al* (2017)[15].	To investigate the possibility of prefabricated optimized footwear achieving adequate plantar pressure reduction, or whether footwear should be individualized, and to compare the response to the therapeutic footwear design of people with diabetes Mellitus with healthy people.	Observational analytical study 3.c B	102 people aged ≥ 18 years old and diagnosed with type 1 or type 2 diabetes Mellitus for at least 6 months and 66 healthy people.	Therapeutic footwear in the prevention of the first foot ulcer in people with diabetes Mellitus.
Results/Conclusions	A prefabricated therapeutic shoe design is suggested that reduces plantar pressure in most people with high plantar pressure but a low risk of ulceration. In this population, choosing an individualized shoe based on plantar pressure has only marginal benefits.			
Premkumar *et al* (2017)[16].	To analyze the role of footwear commonly used in India in inducing early foot ulcers in people with diabetes Mellitus.	Observational descriptive study 4.b B	301 people with type 1 or type 2 diabetes Mellitus with initial foot ulcer due to shoe-related causes, and an equal number of people with diabetic neuropathy or vasculopathy but no current or past history of foot ulcer.	Footwear as a cause or prevention of foot ulcers in people with diabetes Mellitus.
Results/Conclusions	Early foot ulcers can be reduced in people with neuropathy or diabetic vasculopathy by utilizing a hard outsole, soft insole, the existence of midsole, and adjustable front and rear cleats.			
Skafjeld *et al* (2015)[17].	To test the feasibility of foot temperature monitoring in combination with standardized foot care counseling in preventing foot ulcer recurrence in people with diabetes Mellitus.	Experimental study 1.d A	41 people with diabetic neuropathy and a history of a previous foot ulcer were randomly allocated between the intervention target group (n= 21) and the control group (n= 20).	Remote monitoring of foot temperature in the prevention of foot ulcers in people with diabetes Mellitus.
Results/Conclusions	It is feasible to introduce foot temperature monitoring as standard care to prevent foot ulcer recurrence in people with diabetes Mellitus in Norway. No differences in foot ulcer recurrence were detected between the intervention group and the control group.			

Chart 1 – Methodological characteristics and main results of the selected studies.

Authors	Study aim	Design/Evidence Level/ Degree of Recommendation	Participants	Phenomenon of interest
Ulbrecht *et al* (2014)[18].	To analyze the effectiveness of in-shoe orthoses, designed based on the shape and plantar pressure, in reducing the recurrence of plantar ulcers of the metatarsal head.	Controlled experimental study 1.c A	130 people with diabetes, peripheral neuropathy and a history of plantar ulcer of the metatarsal head, were randomly assigned to the experimental group (n= 66) or the control group (n= 64).	Orthotics in the prevention of recurrence of plantar ulcer of the metatarsal head in people with diabetes Mellitus.
Results/Conclusions	Orthoses designed based on plantar shape and pressure is more effective in reducing metatarsal head plantar ulcer recurrence compared to standard orthoses, but do not reduce non-ulcerative lesions.			