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Footwear and insole design features to prevent foot ulceration in people with diabetes: a systematic review protocol

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1 Footwear and insole design features to prevent foot ulceration in people with diabetes: A systematic
2 review protocol

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21 **Review title**

22 Footwear and insole design features to prevent foot ulceration in adults with diabetes: A systematic
23 review protocol

24 **Review question/objective**

25 The aim of this systematic review is to identify the key design features of footwear and insoles which
26 are used to offload the plantar surface of the foot to prevent foot ulceration in adults with diabetes.

27 More specifically, the objectives are to identify the key design features of footwear and insoles to
28 offload the plantar surface of the foot with regard to:

- 29
- 30 • profile/shape of the insole, shoe upper and shoe outsole
 - 31 • material type and properties of the insole and shoe outsole
 - modifications made to the insole and shoe outsole

- fabrication techniques used for the insole and shoe

33 **Background**

34 Diabetes is a disease with devastating multi-factorial complications which causes an economic
35 burden to healthcare providers.¹ The global prevalence of diabetes was reported at 336 million people
36 in 2011 and is expected to rise to 552 million by 2030.² In the United Kingdom (UK) around 1.2 million
37 adults (5.7% of the adult population) are diagnosed with diabetes. This figure is anticipated to grow by
38 a further 1.4% over the next 15 years.³ It is expected that 25% of people with diabetes will develop a
39 foot ulcer at some point.⁴ Foot ulceration is a limb and life threatening condition known to precede
40 80% of all diabetic lower limb amputations.⁵

41 Diabetic foot amputation is associated with poor quality of life and high rates of mortality.⁶ Following
42 primary foot amputation, the five-year mortality rate is in the region of 44%.¹ Estimates of the
43 National Health Services (NHS) annual expenditure for the treatment of the diabetic ulcerated foot
44 were approximately £591 million,¹ whilst indirect costs associated with loss of productivity, sickness
45 and informal care in the UK were estimated at £14 billion for 2010-2011.⁷

46
47 Approximately 30% of people with diabetes will develop peripheral neuropathy.⁴ Diabetic peripheral
48 neuropathy (DPN) is a risk factor for the development of foot ulceration. There are three types of
49 DPN: sensory, motor and autonomic. Sensory neuropathy is a loss of the body's protective feedback
50 mechanism in response to pain or touch.⁸ Motor neuropathy can cause changes in joint mobility and
51 strength, foot structure/deformity and plantar foot pressures⁹⁻¹² whilst autonomic neuropathy
52 contributes to plantar tissue quality loss.¹³⁻¹⁵ Areas at increased susceptibility of ulceration are often in
53 the forefoot region, where the combination of loss of protective sensory feedback, tissue ischemia and
54 elevated plantar pressure loading can result in ulceration.¹⁶

55
56 Elevated dynamic plantar pressures during locomotion are known to contribute to the development of
57 diabetic foot ulcers when in the presence of neuropathy.¹⁷ Reducing high plantar loads or foot
58 pressures is therefore one mechanism by which foot ulceration maybe prevented.¹⁸⁻¹⁹
59 Recommendations for the prevention of diabetic foot ulcer are multidisciplinary and holistic in their
60 approach. However, offloading footwear and insoles has been recognized as one important element
61 of the foot ulcer prevention strategy.

62
63
64 An initial search of the literature published prior to September 2016 was completed using the following
65 databases: AMED, EMBASE, MEDLINE, BNI, CINAHL, the Cochrane Database of Systematic
66 Reviews and PROSPERO databases, and the Joanna Briggs Institute Database of Systematic
67 Reviews and Implementation Reports. This initial literature search suggests that there is a general
68 consensus that footwear and insoles are effective in reducing the load under the foot and preventing
69 ulceration.^{20-23,26} However an evaluation of the specific design features and modes of action that
70 function to alter the load under the foot has not been comprehensively reported. Paton et al (2011)

71 focused on the effectiveness of insoles used in Randomized Controlled Trial's (RCT's) before 2008
72 but did not include the specification or design of the insoles used within the comparative studies.²¹
73 The reviews by Bus et al (2015) and van Netten et al (2016) presented a more comprehensive
74 analysis of factors for preventing foot ulceration and re-ulceration in the at-risk patient with
75 diabetes.^{22,23} Their findings highlighted only one study which emphasised the design features of
76 footwear and insoles using a prescription algorithm²⁴ and one study that used in-shoe pressure
77 measurements to inform the footwear.²⁵ Heuch and Gomersall's (2016) systematic review identified
78 three studies of poor quality evidence to support methods of offloading for preventing primary diabetic
79 foot ulceration only. Whilst the components of the insole and footwear used to offload were presented
80 from the studies, the key design features and mode of action were not identified, as was the lack of
81 exploration of offloading on those with a past history of ulceration.²⁶

82

83 None of the reviews to date have included robust studies which investigate the effectiveness of
84 particular design features for insole and footwear manufacture. Without this important clinically
85 relevant information, those tasked with providing insoles for people with diabetes are unable to
86 determine which insole and footwear type or design is best for preventing foot ulceration. This should
87 be related to the design features of the footwear or insole, and should include details associated with
88 the profile/shape, material properties, integrated modifications and fabrication.^{27,28} A scoping of the
89 existing literature, using identical databases as in the initial search, reveals a large variety of design
90 features for insoles and footwear that merits further exploration.

91

92 Therefore the purpose of this systematic literature review is to bridge the existing gap in the literature
93 and identify the key design features of footwear and insoles used to offload the plantar surface of the
94 foot to prevent foot ulceration in people with diabetes. It is anticipated that this information will inform
95 a protocol for the clinical design of therapeutic insoles and footwear within a RCT to offload the foot
96 and reduce ulcer risk in people with diabetes and neuropathy.

97

98 **Inclusion and exclusion criteria**

99 **Types of participants**

100 This review will consider studies that include adults over 18 years with type 1 or type 2 diabetes,
101 regardless of duration of diabetes, history of previous foot ulceration or other co-morbidities, without
102 any amputation or Charcot arthropathy. It will exclude studies of people with current foot ulceration on
103 entry to the study.

104 **Types of intervention(s)**

105 Studies will be considered that evaluate the effectiveness of any footwear and/or insole design
106 features intended to offload the plantar surface of the diabetic foot for ulcer prevention.

107 Studies will be included if they make one of the following comparisons:

108 1. Footwear and/or insole design feature compared to another therapeutic footwear and/or
109 insole design feature

110 2. Footwear and/or insole design feature compared to no intervention

111 Footwear and/or insole design features will be defined as any identifiable and distinguishing
112 characteristic integral to the footwear or insole device. These may include, but are not limited to:
113 footwear outsole profile variations (heel height, rocker modifications), footwear upper style variations
114 (boots, shoes, sandals), insoles/orthoses profile variations (with/without arch support, metatarsal bars,
115 1st ray cut-outs, kinetic wedges, internal and external posting), differences in insole/orthosis material
116 properties (rigid or soft devices), shaped padding applied to the foot (plantar covers, ring pads), and
117 variations in the design and stiffness of ankle foot orthosis used to restrict ankle joint dorsiflexion
118 (rigid/semi-rigid). Excluded will be studies that investigate offloading devices intended for the
119 treatment of foot ulceration as the indications and rationale for use are not consistent with the
120 objectives of this systematic review.

121

122 **Types of outcomes**

123 This review will consider studies that include either of the following

124 primary outcome measures of foot ulceration incidence or frequency

125 and/or secondary outcome measures of:

126 • Any standardized kinetic or kinematic outcome measure indicating loading or offloading the
127 plantar foot: such as plantar pressure (eg reduction in mean peak pressure, reduction in
128 pressure time integral, increase in total contact area, and changes in the dynamic measures
129 of centre of pressure trajectory or velocity).

130 • Any standardized clinical measure indicating loading/offloading of the plantar foot: such as
131 callus/lesion reduction.

132 • Any side effects/adverse events as a result of the design features

133

134 **Types of studies**

135 This review will consider both experimental and epidemiological study designs including randomized
136 controlled trials, non-randomized controlled trials, quasi-experimental, before and after case series
137 studies, prospective and retrospective cohort studies and analytical cross sectional studies for
138 inclusion.

139 This review will exclude qualitative studies, case reports and systematic reviews.

140

141 **Search strategy**

142 The search strategy aims to find both published and unpublished studies. A three-step search
143 strategy will be utilized. An initial limited search of MEDLINE and CINAHL will be undertaken followed
144 by analysis of the text words contained in the title and abstract, and of the index terms used to
145 describe the article. A second search using all identified keywords and index terms will then be
146 undertaken across all included databases. Thirdly, the reference list of all identified reports and
147 articles will be searched for additional studies. A research librarian will assist in designing search
148 terms for various databases. Studies published in English will be considered for inclusion in this
149 review. Studies published from inception to present will be considered for inclusion in this review.

150

151 The databases to be searched include:

152 AMED (EBSCO), CINAHL, MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials.
153 Joanna Briggs Institute Database of Systematic Reviews, and PROSPERO will be used to
154 check the reference list of relevant systematic reviews to ensure all appropriate papers are included in
155 the search.

156 The search for unpublished studies and gray literature will include:

157 EThOS, Pearl, Web of Science, Google Scholar, SIGLE

158

159 Initial keywords and MeSH terms to be used will be:

- 160 1. diabet*
- 161 2. diabetes mellitus [MeSH]
- 162 3. foot feet
- 163 4. neuropath*
- 164 5. ulcer*
- 165 6. pressure [MeSH]
- 166 7. gait
- 167 8. walking
- 168 9. time
- 169 10. offload*
- 170 11. off-load*
- 171 12. insole*
- 172 13. orthos*
- 173 14. orthotic devices [MeSH]
- 174 15. therapeutic footwear
- 175 16. shoes[MeSH]
- 176 17. footwear
- 177 18. rocker

178

179 **Assessment of methodological quality**

180 Two independent reviewers (RC / JP) will assess papers selected for retrieval. The reviewers will
181 initially scan the titles and abstracts to exclude papers that do not align with the inclusion criteria. Full
182 text articles will be obtained for papers that meet the inclusion criteria or where uncertainty exists. The
183 full text articles will then be read and those that fulfil the inclusion criteria will be assessed for
184 methodological validity prior to inclusion in the review. Papers selected for retrieval will be assessed
185 using standardized critical appraisal instruments from the Joanna Briggs Institute System for the
186 Unified Management, Assessment and Review of Information (JBI SUMARI) (Appendix I). Any
187 disagreements that arise between the reviewers will be resolved through discussion, or with two other
188 reviewers (JF / JML).

189

190 **Data extraction**

191 The data will be extracted by two independent reviewers. Data will be extracted from papers included
192 in the review using the standardized data extraction tool from JBI SUMARI (Appendix III). The data
193 extracted will include specific details about the footwear and/or insole design features, populations,
194 study methods and outcomes of significance to the review question and specific objectives. If there is
195 information missing in relevant studies, the corresponding author will be contacted and given the
196 opportunity to clarify the information.

197 **Data synthesis**

198 Quantitative data will, where possible be pooled in statistical meta-analysis using JBI SUMARI. All
199 results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data)
200 and weighted mean differences (for continuous data) and their 95% confidence intervals will be
201 calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square and
202 also explored using subgroup analyses based on the different study designs included in this review.
203 Where statistical pooling is not possible the findings will be presented in narrative form including
204 tables and figures to aid in data presentation where appropriate.

205 **Conflicts of interest**

206 There is no conflict of interest to declare.

207 **Acknowledgements**

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211 author(s) and not necessarily those of the National Health Service (NHS), the NIHR or the
212 Department of Health.

213

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316

317 **Appendix I: Appraisal instruments**

318 **SUMARI Appraisal instrument**

319

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer Date

Author Year Record Number

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were participants blinded to treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was allocation to treatment groups concealed from the allocator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were those assessing outcomes blind to the treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were the control and treatment groups comparable at entry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were groups treated identically other than for the named interventions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in the same way for all groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include Exclude Seek further info.

Comments (Including reason for exclusion)

320

321

322

JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer Date

Author Year Record Number

	Yes	No	Unclear	Not Applicable
1. Was study based on a random or pseudo-random sample?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the criteria for inclusion in the sample clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If comparisons are being made, was there sufficient descriptions of the groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

323

324

JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

Reviewer Date

Author Year Record Number

	Yes	No	Unclear	Not Applicable
1. Is sample representative of patients in the population as a whole?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are the patients at a similar point in the course of their condition/illness?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has bias been minimised in relation to selection of cases and of controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include Exclude Seek further info.

Comments (Including reason for exclusion)

325
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330 JBI Critical Appraisal Checklist for Analytical Cross Sectional Studies

331 Reviewer _____ Date _____

332

333 Author _____ Year _____ Record Number _____

334

	Yes	No	Unclear	Not applicable
1. Were the criteria for inclusion in the sample clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the study subjects and the setting described in detail?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was the exposure measured in a valid and reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were objective, standard criteria used for measurement of the condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were confounding factors identified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were strategies to deal with confounding factors stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes measured in a valid and reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

335 Overall appraisal: Include Exclude Seek further info

336 Comments (Including reason for exclusion)

337 _____

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339 _____

340

341

**JBI Data Extraction Form for
Experimental / Observational Studies**

Reviewer Date

Author Year

Journal Record Number

Study Method

RCT Quasi-RCT Longitudinal

Retrospective Observational Other

Participants

Setting _____

Population _____

Sample size

Group A _____ Group B _____

Interventions

Intervention A _____

Intervention B _____

Authors Conclusions:

Reviewers Conclusions:

342

343

344 **Appendix II: SUMARI Data extraction instruments**

Study results

Dichotomous data

Outcome	Intervention () number / total number	Intervention () number / total number

Continuous data

Outcome	Intervention () number / total number	Intervention () number / total number

345

346

347