

**Table S1.** Risk of bias assessment: QUIPS tool.

	Study Participation							Study Attrition					Prognostic Factor					Outcome Measurement		Study Confounding							Statistical Analysis and Reporting													
	Source or target population	Method identification population	Recruitment period	Place of recruitment	Inclusion and exclusion criteria	Adequate study population	Baseline characteristics	Summary study participation	Proportion baseline sample available	Attempts collecting information drop-outs	Reasons and impact drop-outs	Description drop-outs	No difference drop-outs and completers	Summary study attrition	Definition prognostic factor	Valid and reliable measurement	Continuous variables or cut-points	Method and setting	Proportion data available	Method missing data	Summary prognostic factor	Definition of outcome	Valid and reliable measurement	Method and setting	Summary outcome measurement	Important confounders measured	Definition confounders	Valid and reliable measurement	Method and setting	Method missing data	Confounders accounted for in study design	Confounders accounted for in analysis	Summary study confounding	Presentation of analytical strategy	Appropriate strategy model building	Statistical model adequate for study design	Reporting of results	Summary statistical analysis and reporting		
Armstrong et al. 1998 [1]	+	-	-	-	±	?	+	H	+	+	+	+	+	+	L	+	+	+	+	+	L	-	?	+	H	+	+	+	+	+	+	+	L	±	+	+	+	+	L	
Armstrong et al. 2004 [2]	+	±	-	-	±	?	+	H	+	+	+	+	+	+	L	-	+	+	+	+	M	-	-	?	H	±	±	+	+	+	±	-	-	H	+	-	-	+	M	
Chantelau et al. 1994 [3]	±	-	-	-	+	?	±	H	+	+	+	+	+	+	L	+	±	+	+	+	M	-	±	+	H	±	-	?	+	+	-	-	-	H	+	-	-	+	M	
Connor et al. 2004 [4]	+	-	+	-	+	±	+	M	?	?	?	?	?	?	H	±	-	-	?	+	+	H	±	±	±	H	+	±	±	+	+	-	-	-	H	+	-	-	+	M
Crews et al. 2016 [5]	+	-	+	±	+	?	+	M	+	-	+	+	±	±	L	+	+	+	+	±	±	L	±	±	+	M	±	+	+	+	-	+	+	M	+	±	+	±	M	
Deschamps et al. 2016 [6]	+	-	+	+	+	?	+	L	+	+	+	+	+	+	L	+	+	+	+	+	L	±	±	+	M	+	+	±	+	+	-	-	-	H	+	-	-	+	M	
Jarl et al. 2017 [7]	+	-	-	-	+	?	±	H	+	+	+	+	+	+	L	±	+	±	+	+	+	M	+	-	+	M	-	-	?	?	+	-	-	-	H	-	-	-	H	
Kästenbauer et al. 2001 [8] and Grimm et al. 2004 [9]	+	-	-	-	+	+	+	M	+	-	-	-	-	-	H	+	+	+	+	+	-	L	+	-	+	M	+	+	+	+	±	±	±	M	+	±	±	+	M	
Lavery et al. 2003 [10]	+	-	-	+	-	+	±	H	+	+	+	+	+	+	L	+	+	+	+	+	L	-	-	?	H	±	+	+	?	+	±	-	-	H	+	-	-	+	M	
Ledoux et al. 2013 [11]	+	-	+	+	+	+	+	L	±	+	+	-	+	M	+	±	+	±	+	?	M	+	-	+	M	+	+	+	+	?	+	+	L	+	+	+	+	L		
Lemaster et al. 2003 [12]	±	-	-	+	+	+	+	M	+	+	+	+	+	+	L	+	±	±	+	+	M	+	+	+	L	+	+	+	+	?	+	+	L	+	+	+	+	L		
Mueller et al. 2013 [13]	+	+	+	+	+	+	+	L	+	+	+	+	+	+	L	+	±	+	+	+	L	+	+	+	L	+	+	+	+	-	-	-	H	+	-	-	+	M		
Murray et al. 1996 [14]	+	-	-	+	+	?	±	M	+	+	+	+	+	+	L	±	+	-	+	+	M	±	±	+	M	±	±	+	+	+	-	-	-	H	+	-	-	?	M	
Najafi et al. 2017 [15]	+	-	-	+	+	?	-	H	+	-	+	-	?	?	M	+	+	+	?	+	-	M	+	+	+	L	±	±	±	+	-	-	-	H	+	-	-	±	H	
Pham et al. 2000 [16] and Caselli et al. 2002 [17]	+	-	-	+	-	+	+	M	+	+	+	+	+	+	L	+	+	+	+	+	L	-	?	?	H	+	+	+	+	+	+	+	+	L	+	+	+	+	L	
Qiu et al. 2015 [18]	+	+	+	+	+	+	+	L	+	+	+	+	+	+	L	±	?	+	+	+	M	-	?	+	H	+	+	+	+	+	±	±	M	±	-	-	+	H		
Schneider et al. 2019 [19]	+	-	-	+	+	-	+	H	+	-	-	-	±	M	+	+	+	+	+	?	L	-	+	?	H	+	+	+	+	±	-	-	-	H	+	-	-	+	M	
Ullbrecht et al. 2014 [20]	+	+	-	+	+	+	+	L	+	+	+	+	+	+	L	+	+	+	+	+	L	+	+	+	L	+	±	+	?	+	-	-	M	+	-	-	+	M		
Van Netten et al. 2018 [21]	+	-	+	+	+	±	+	L	+	+	+	+	+	+	L	+	+	+	+	+	L	+	±	+	M	+	±	±	±	+	-	-	-	M	+	±	±	+	M	
Waaijman et al. 2014 [22]	+	-	-	-	+	+	+	L	+	?	-	+	+	M	+	+	+	+	?	-	M	+	+	+	L	+	+	+	+	+	+	+	+	L	+	+	+	+	L	

+ = yes (green), ± = partial (orange), - = no (red), ? = unsure (yellow). Summary domain score: L = low (green), M = moderate (orange) and H = high risk of bias (red).

**Table S2.** Risk of bias assessment: 21-item score.

	Total Score* (Out of 17)	21. No Commercial Interests	20. Conclusions Supported by Findings	19. Balanced Discussion	18. Free from Errors of Reporting	17. Comparable Results from Participating Centers	16. Cohort Performance as Expected in Clinical Practice	15. Appropriate Statistical Methods are Used	13.Primary Outcome in >75% of those Recruited	12. Completion of Recruitment	11. Clinical Researcher Blinded to Group	10. Assessor Primary Outcome Blinded to Group Allocation Primary Outcome	9. Primary Outcome of Direct Clinical Relevance	8. Power Calculation	5. Other Components of Care	4. Description Intervention	2. Appropriate Study Population	1. Appropriate Definition
Armstrong et al. 1998 [1]	11	+	+	-	+	+	+	+	+	?	-	-	+	-	+	+	+	-
Armstrong et al. 2004 [2]	8	+	+	-	?	?	?	+	+	?	?	?	+	-	+	+	+	-
Chantelau et al. 1994 [3]	11	+	+	-	+	+	+	+	+	?	?	?	+	-	+	+	+	-
Connor et al. 2004 [4]	9	+	+	+	+	+	+	+	+	?	?	?	?	-	-	?	+	-
Crews et al. 2016 [5]	10	+	+	+	-	-	?	+	+	?	-	-	+	-	+	+	+	+
Deschamps et al. 2016 [6]	9	+	+	-	+	?	+	+	+	?	?	?	+	-	-	+	+	-
Jarl et al. 2017 [7]	12	+	+	+	+	+	+	-	+	?	?	?	+	-	+	+	+	+
Kästenbauer et al. 2001 [8] and Grimm et al. 2004 [9]	13	+	+	+	+	+	+	+	+	?	?	?	+	-	+	+	+	+
Lavery et al. 2003 [10]	10	+	+	+	+	?	?	+	+	?	?	?	+	-	+	+	+	-
Ledoux et al. 2013 [11]	11	+	+	+	+	+	?	+	+	?	?	?	+	-	?	+	+	+
Lemaster et al. 2003 [12]	11	+	+	?	+	?	?	+	+	?	+	+	+	-	-	+	+	+
Mueller et al. 2013 [13]	15	+	+	+	+	+	?	+	+	+	+	+	+	+	-	+	+	+
Murray et al. 1996 [14]	10	+	+	-	+	+	+	+	+	?	-	-	+	-	-	+	+	-
Najafi et al. 2017 [15]	12	+	+	+	+	-	?	+	+	?	?	?	+	-	+	+	+	+
Pham et al. 2000 [16] and Caselli et al. 2002 [17]	9	+	+	-	+	?	+	+	+	?	?	?	+	-	-	+	+	-
Qiu et al. 2015 [18]	8	+	?	-	+	+	-	+	+	?	?	?	+	-	-	+	+	-
Schneider et al. 2019 [19]	11	+	+	+	+	+	+	+	+	?	?	?	+	-	-	+	+	-
Ulbrecht et al. 2014 [20]	16	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Van Netten et al. 2018 [21]	13	+	+	+	+	?	+	+	+	?	-	+	+	-	+	+	+	+
Waaijman et al. 2014 [22]	12	+	+	+	+	?	+	+	+	?	-	+	+	-	-	+	+	+

Question 3, 6, 7 and 14 of the 21-item score are excluded (see Methods), so 17 items in total. + = yes (green), ? = unsure/unknown (orange), - = no (red). \* Total score is sum of +’s out of 17.

Table S3. Risk of bias assessment: SIGN.

	Internal Validity												Overall Assessment	
	1.1 Clear research question and listed inclusion / exclusion criteria	1.2 Comprehensive literature search	1.3 Two people selected studies	1.4 Two people extracted data	1.5 Status of publication was not used as an inclusion criterion	1.6 Excluded studies are listed	1.7 Relevant characteristics of included studies are provided	1.8 Assessment and reporting of quality of included studies	1.9 Scientific quality of included studies appropriately used	1.10 Appropriate methods used to combine individual study findings	1.11 Likelihood of publication bias was assessed appropriately	1.12 Conflicts of interest are declared	2.1 Overall assessment of the methodological quality	2.2 Results are directly applicable to the patient group targeted
Crawford et al. 2007 [23]	yes	yes	yes	can't say	yes	yes	no	yes	yes	yes	no	no	high quality	yes

**Table S4.** Plantar pressure - ulcer development.

Reference	Population	Risk of Bias	Ulcer Outcome	Factor + Outcomes	Conclusion
Crawford et al. 2007 [23] Meta-analysis	Pham et al. 2000 and Lavery et al. 2003	SIGN: High quality study	Pham et al. 2000 Ulcerated: 29% ( <i>n</i> = 73) Lavery et al. 2003 Ulcerated: 16% ( <i>n</i> = 263) Total Ulcerated: 21% ( <i>n</i> = 336)	Barefoot PP: Pham et al. 2000 Weight: 36.59% SMD: 0.62, 95% CI: (0.35, 0.90) Lavery et al. 2003 Weight: 63.41% SMD: 0.38, 95% CI: (0.25, 0.52) Total Weight: 100% SMD: 0.47, 95% CI: (0.24; 0.77)	Associated ( $Z = 4.05, p < 0.0001$ )
Pham et al. 2000 [16] and Caselli et al. 2002 [17] * Prospective cohort study Period: not presented Location: Boston, MA; San Antonio, TX; San Francisco, CA, USA (multicenter)	N: 248 Male: 50% Age: 58 ± 12 years Type 2: 80% Neuropathy: 84% Risk classification: not presented	QUIPS: M-L-L-H-L-L 21-item score: 9/17	At 30 (6–40) months: Ulcerated: 29% ( <i>n</i> = 73)	Barefoot PP (kPa): Ulcerated: 706 ± 373 Non-ulcerated: 522 ± 255	Associated ( <i>p</i> < 0.001)
			At 30 (6–40) months: ≥588 kPa: 45% ulcerated ( <i>n</i> = 173) <588 kPa: 34% ulcerated ( <i>n</i> = 75)	Barefoot cut-off PP ≥588 kPa	Associated (OR: 3.2, 95% CI: (2.0; 5.1), <i>p</i> < 0.001 (univariate), OR: 2.0, 95% CI: (1.2; 3.3), <i>p</i> = 0.007 (multivariate Pham et al. 2000) and OR: 1.8, 95% CI: (1.0-3.0), <i>p</i> = 0.03 (multivariate Caselli et al. 2002))
			At 30 (6–40) months: Number of participants and percentage ulceration per group not presented	Barefoot forefoot-to-rearfoot PP ratio >2	Associated (OR: 2.7, 95% CI: (1.7; 4.3), <i>p</i> = 0.001 (univariate) and OR: 1.8, 95% CI: (1.1; 3.2), <i>p</i> = 0.03 (multivariate))
Lavery et al. 2003 [10] Prospective cohort study Period: not presented Location: San Antonio, TX, USA (monocenter)	N: 1666 Male: 50.4% Age: 69.1 ± 11.1 years Type 2: not presented Neuropathy: not presented Risk classification: not presented	QUIPS: H-L-L-H-H-M 21-item score: 10/17	At 24 (20–29) months: Ulcerated: 16% ( <i>n</i> = 263)	Barefoot PP (kPa): Ulcerated: 955 ± 264 Non-ulcerated: 851 ± 273	Associated ( <i>p</i> < 0.001)
			At 24 (20–29) months: >875 kPa: 17% ulcerated <875 kPa: 10% ulcerated Number of participants per group not presented †	Cut-off PP: >875 kPa	Associated (OR: 2.0, 95% CI: (1.4; 2.9), <i>p</i> = 0.0001)
Kästenbauer et al. 2001 [8] and Grimm et al. 2004 [9] † Prospective cohort study Period: 1994–1998 Location: Vienna, Austria (monocenter)	N: 187 Male: 55% Age: 58.6 years Type 2: 100% Neuropathy: 38% Risk classification: not presented	QUIPS: M-H-L-M-M-M 21-item score: 13/17	At 3.6 years (mean): Ulcerated: 5% ( <i>n</i> = 10)	Barefoot PP (kPa): Ulcerated: 785 (705; 1155) Non-ulcerated: 605 (430; 800)	Associated ( <i>p</i> < 0.01)
			At 3.6 years (mean): Number of participants and percentage ulceration per group (>2 SD / <2 SD) not presented	Barefoot cut-off PP >2 SD compared to a healthy participant in at least one forefoot region	Associated (RR: 6.3, 95% CI: (1.2; 32.7), <i>p</i> = 0.0291)
Ulbrecht et al. 2014 [20] Prospective randomized controlled trial Period: not presented Location: PA; IL; CA; AZ; OH; TX; CO, USA (multicenter)	N: 130 Male: 78% Age: 59.5 years Type 2: not presented Neuropathy: 100% Risk classification: IWGDF 3: 100%	QUIPS: L-L-L-L-M-M 21-item score: 16/17	At 15 months: Ulcerated: 17% ( <i>n</i> = 22) Non-ulcerative lesions: 25% ( <i>n</i> = 32)	Barefoot PP (kPa): Ulcerated: 1131 Non-ulcerative lesions: 1042 Non-ulcerated: 984	Associated ( <i>p</i> = 0.04)

Deschamps et al. 2016 [6] Retrospective cohort study Period: 2010–2011 Location: Leuven; Aalst, Belgium (multicenter)	N: 97, 194 feet Numbers below for feet: Male: 68% Age: 61.6 years Type 2: 72% Neuropathy: 51% Risk classification: IWGDF 0: 41%, IWGDF 1: 3%, IWGDF 2: 12%, IWGDF 3: 44%	QUIPS: L-L-L-M-H-M 21-item score: 9/17	At 42.7 months (mean): Ulcerated: 7% ( $n = 7$ )	Barefoot PP (kPa): Ulcerated: $1332.4 \pm 207.8$ Non-ulcerated: $814.8 \pm 247.6$	Associated ( $r = 0.462$ , $p < 0.001$ ) §
Murray et al. 1996 [14] Prospective cohort study Period: not presented Location: Manchester, UK (multicenter)	N: 63 Male: 68% Age: 62 (52; 67) years Type 2: 60% Neuropathy: 100% Risk classification: not presented	QUIPS: M-L-M-M-H-M 21-item score: 10/17	At 15.4 (10–22) months: Ulcerated: 10% ( $n = 6$ )  At 15.4 (10–22) months: Incidence of ulcers by individual area of the foot: <981 kPa: 0.3% ulcerations ( $n = 3/886$ ) ≥981 kPa: 1.6% ulcerations ( $n = 4/248$ )	Barefoot PP (kPa): Ulcerated: 1451 (1098; 1952) Non-ulcerated: 1677 (1461; 2099)  Cut-off PP: ≥981 kPa	Not associated ( $p = 0.14$ )  Associated (RR: 4.7, 95% CI: (1.2; 18.9), $p = 0.04$ )
Qiu et al. 2015 [18] Prospective before and after study Period: 2012 Location: Shijazhuang, Hebei, China (monocenter)	N: 65 Male: 45% Age: 59 (40–78) years Type 2: 100% Neuropathy: not presented Risk classification: not presented	QUIPS: L-L-M-H-M-H 21-item score: 8/17	At 2 years: Ulcerated: 3% ( $n = 2$ )	Barefoot PP change over 2 years in the metatarsals: Barefoot PP changes per group not presented. Barefoot PTI change over 2 years in the metatarsals: Barefoot PTI changes per group not presented.	Not associated ( $p > 0.05$ )  Not associated ( $p > 0.05$ )
Waaijman et al. 2014 [22] <sup>†</sup> Prospective randomized controlled trial Period: 2007–2010 Location: the Netherlands (multicenter) Shoes: custom-made orthopedic footwear with or without pressure optimization	N: 171 Male: 82.5% Age: $63.3 \pm 10.1$ years Type 2: 71.3% Neuropathy: 100% Risk classification: IWGDF 3: 100%	QUIPS: L-M-M-L-L-L 21-item score: 12/17	At 18 months: Plantar ulcers: 42% ( $n = 71$ )  At 18 months: Ulcers from unrecognized trauma: 24% ( $n = 41$ )	Barefoot PP (kPa): Plantar ulcers: $1042 \pm 260$ No plantar ulcers: $935 \pm 307$ In-shoe PP (measured quarterly during follow-up) (kPa): Plantar ulcers: $261 \pm 83$ No plantar ulcers: $246 \pm 77$ Barefoot PP (kPa): Ulcers from unrecognized trauma: $849 \pm 375$ No ulcers from unrecognized trauma: $699 \pm 393$ In-shoe PP (measured quarterly during follow-up) (kPa) Ulcers from unrecognized trauma: $212 \pm 99$ No ulcers from unrecognized trauma: $178 \pm 82$	Associated (OR: 1.18, 95% CI: (1.09; 1.27), $p < 0.0001$ )  Not associated (OR: 1.21, 95% CI: (0.95; 1.53), $p = 0.120$ )  Associated (OR: 1.12, 95% CI: (1.05; 1.21), $p = 0.001$ (univariate), OR: 1.11, 95% CI: (1.00; 1.22), $p =$ 0.040 (multivariate))  Associated (OR: 1.38, 95% CI: (1.05; 1.81), $p = 0.023$ )
Ledoux et al. 2013 [11] Prospective cohort study Period: 1996–2002	N: 591 Male: 98.1% Age: 67 years	QUIPS: L-M-M-M-L-L 21-item score: 11/17	At 2.4 (0–6.2) years: Ulcerated: 8% ( $n = 47$ )	In-shoe PP (kPa): Ulcerated: 219 Non-ulcerated: 194	Not associated (HR: 1.27, 95% CI: (0.89; 1.74), $p = 0.171$ )

Location: WA, USA (monocenter) Shoes: "usual" shoes	Type 2: not presented Neuropathy: 50% Risk classification: not presented	In-shoe PTI (kPa-s): Ulcerated: 89 Non-ulcerated: 79	Not associated (HR: 1.25, 95% CI: (0.94; 1.52), $p = 0.115$ )
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All plantar pressures are measured during baseline unless otherwise mentioned. Results expressed as mean  $\pm$  standard deviation, median (quartile 1; quartile 3) or mean (minimum-maximum). Abbreviations: N = number of participants, type 2 = type 2 diabetes, PP = peak pressure, PTI = peak pressure gradient, kPa = kilo Pascal, kPa-s = kilo Pascal times seconds, 95% CI = 95% confidence interval, OR = odds ratio, RR = relative ratio, HR = hazard ratio, SMD = standardized mean difference,  $r$  = Pearson correlation coefficient. Z = standard score of overall effect. Quips domains: (1) Study participation, (2) Study attrition, (3) Prognostic factor measurement, (4) Outcome measurement, (5) Study confounding, (6) Statistical analysis and reporting. L = low, M = moderate and H = high risk of bias. \* 10 participants less in Caselli et al. 2002 than in Pham et al. 2000, reason of exclusion undefined in Caselli et al. 2002. The results of "Barefoot PP (kPa)" can be found in Pham et al. 2000, the results of "Barefoot cut-off PP  $\geq 588$  kPa" can be found in both Pham et al. 2000 and Caselli et al. 2002 and the results of "Barefoot forefoot-to-rearfoot PP ratio  $>2$ " can be found in Caselli et al. 2002. † Lavery et al. 2003 eliminated participants without a loss of protective sensation for this association, but the number of participants for this group is not presented. ‡ 36 participants less in Grimm et al. 2004 than in Kästenbauer et al. 2001, 151 of the 187 participants completed the study per protocol and that constituted the basis of the analysis of Grimm et al. 2004. The result of "Barefoot cut-off PP  $> 2$  SD" can be found in Kästenbauer et al. 2001 and the results of "Barefoot PP (kPa)" can be found in Grimm et al. 2004. § Deschamps et al. 2016, analysis based on 109 participants (218 feet) and 7 ulcerations using data provided by the authors. † Waaajman et al. 2014, plantar ulcers = any plantar ulcer; ulcers from unrecognized trauma = ulcer recurrence at previous ulcer location and not to be the result of acute trauma. A significance level of  $p < 0.10$  was used.

**Table S5.** Weight-bearing activity - ulcer development.

Reference	Population	Risk of Bias	Ulcer Outcome	Factor + Outcomes	Conclusion
Armstrong et al. 2004 [2] Prospective cohort study Period: not presented Location: USA (not presented)	N: 100 Male: 95% Age: $68.5 \pm 10.0$ years Type 2: not presented Neuropathy: 100% Risk classification: IWGDF 2: 68% and IWGDF 3: 32%	QUIPS: H-L-M-H-H-M 21-item score: 8/17	At $37.1 \pm 12.3$ weeks (mean): Ulcerated: 8% ( $n = 8$ )	Average daily activity* (entire study period): Ulcerated: $809.0 \pm 612.2$ Non-ulcerated: $1394.5 \pm 868.5$  Coefficient of variation in daily activity (%): Ulcerated: $96.4 \pm 50.3$ Non-ulcerated: $44.7 \pm 15.4$	Associated ( $p = 0.03$ )   Associated ( $p = 0.0001$ )
Lemaster et al. 2003 [12] Prospective cohort study Period: 1997–1998 Location: WA, USA (multicenter)	N: 390 Male: 77% Age: $62.5 \pm 9.0$ years Type 2: not presented Neuropathy: 58% Risk classification: IWGDF 3: 100%	QUIPS: M-L-M-L-L-L 21-item score: 11/17	At 2 years: Least active: 17% ulcerated ( $n = 22/133$ ) Moderately active: 13% ulcerated ( $n = 18/134$ ) Most active: 13% ulcerated ( $n = 16/123$ )	Activity group (activity measured every 17 <sup>th</sup> week during follow-up): Least active: $<4.5$ h per day Moderately active: $4.5$ – $7.4$ h per day Most active: $\geq 7.5$ h per day	Not associated ( $p > 0.05$ )
Waaajman et al. 2014 [22] † Prospective randomized controlled trial Period: 2007–2010 Location: the Netherlands (multicenter)	N: 171 Male: 82.5% Age: $63.3 \pm 10.1$ years Type 2: 71.3% Neuropathy: 100% Risk classification: IWGDF 3: 100%	QUIPS: L-M-M-L-L-L 21-item score: 12/17	At 18 months: Plantar ulcers: 42% ( $n = 71$ )	Steps per day (7-day period $<3$ months after baseline): Plantar ulcers: $6476 \pm 2574$ No plantar ulcers: $6874 \pm 3980$  Variation in steps per day (7-day period $<3$ months after baseline): Plantar ulcers: $2136 \pm 1098$ No plantar ulcers: $2552 \pm 1586$	Not associated (OR: 0.99, 95% CI: (0.97; 1.01), $p = 0.360$ )  Associated (OR: 0.95, 95% CI: (0.90; 0.99), $p = 0.023$ (univariate), OR: 0.93, 95% CI: (0.89; 0.99), $p = 0.012$ (multivariate))

				At 18 months: Ulcers from unrecognized trauma: 24% ( <i>n</i> = 41)	<p>Steps per day (7-day period &lt;3 months after baseline):</p> <p>Ulcers from unrecognized trauma: 6418 ± 2662</p> <p>No ulcers from unrecognized trauma: 6808 ± 3714</p> <hr/> <p>Variation in steps per day (7-day period &lt;3 months after baseline):</p> <p>Ulcers from unrecognized trauma: 2124 ± 1156</p> <p>No ulcers from unrecognized trauma: 2468 ± 1494</p>	<p>Not associated (OR: 0.99, 95% CI: (0.97; 1.01), <i>p</i> = 0.404)</p> <hr/> <p>Associated (OR: 0.96, 95% CI: (0.91; 1.01), <i>p</i> = 0.096 (univariate), OR: 0.91, 95% CI: (0.86; 0.96), <i>p</i> = 0.001 (multivariate))</p>
Mueller et al. 2013 [13]	<i>N</i> : 29				Steps per day (baseline)	
Prospective randomized controlled trial	Male: 59%	QUIPS: L-L-L-L-H-M		At 12 weeks:	Ulcerated: 5360 ± 1673	
Period: 2009–2011	Age: 64.5 ± 12.5 years	21-item score: 15/17		Ulcerated: 10% ( <i>n</i> = 3)	Non-ulcerated: 5717 ± 1751	Number of ulcerations too low to assess association.
Location: WA, USA (monocenter)	Type 2: 100%				Steps per day (12 weeks)	
	Neuropathy: 100%				Ulcerated: 4654 ± 1211	
	Risk classification: not presented				Non-ulcerated: 5941 ± 1751	
Schneider et al. 2019 [19]	<i>N</i> : 12				Steps per day (baseline):	
Prospective mixed methods study	Male: 33.3%	QUIPS: H-M-L-H-H-M		At 20 weeks:	Ulcerated: 1883.00	
Period: not presented	Age: 59.92 ± 8.68 years	21-item score: 11/17		Ulcerated: 8% ( <i>n</i> = 1)	Non-ulcerated: 3871.80 ± 1367.88	Number of ulcerations too low to assess association.
Location: IL, USA (monocenter)	Type 2: 91.7%				Steps per day (after 20 weeks):	
	Neuropathy: 100%				Ulcerated: 2957.00	
	Risk classification: not presented				Non-ulcerated: 4342.00 ± 1292.09	

Results expressed as mean ± standard deviation. Abbreviations: *N* = number of participants, type 2 = type 2 diabetes, CI = 95% confidence interval, OR = odds ratio. Quips domains: (1) Study participation, (2) Study attrition, (3) Prognostic factor measurement, (4) Outcome measurement, (5) Study confounding, (6) Statistical analysis and reporting. L = low, M = moderate and H = high risk of bias. \* Armstrong et al. 2004, daily activity measured in activity units, which is an undefined measure in Armstrong et al. 2004. † Waaijman et al. 2014, plantar ulcers = any plantar ulcer; ulcers from unrecognized trauma = ulcer recurrence at previous ulcer location and not to be the result of acute trauma. A significance level of *p* < 0.10 was used.

**Table S6.** Footwear adherence - ulcer development.

Reference	Population	Risk of Bias	Ulcer Outcome	Factor + Outcomes	Conclusion
Chantelau et al. 1994 [3] Prospective cohort study Period: not presented Location: Düsseldorf, Germany (monocenter)	N: 51 Male: 59% Age: 63 (60; 67) years Type 2: 71% Neuropathy: not presented Risk classification: IWGDF 3: 100%	QUIPS: H-L-M-H-H-M 21-item score: 11/17	At 4 years: ≥9.6 / 16 h per day: 54% ulcerated ( <i>n</i> = 20/37) <9.6 / 16 h per day: 100% ulcerated ( <i>n</i> = 14/14)	Cut-off adherence ≥9.6/16 h per day	Associated ( <i>p</i> = 0.0002)
Connor et al. 2004 [4] Retrospective cohort study Period: 1996-not presented Location: Hereford, UK (monocenter)	N: 83 Male: 67% Age: 57.0 years Type 2: 69% Neuropathy: 100% Risk classification: IWGDF 3: 100%	QUIPS: M-H-H-H-H-M 21-item score: 9/17	After minimum 2 years: ≥3.5 ulcers per foot per 10 years: 64% of ulcers ( <i>n</i> = 207), 37% of participants ( <i>n</i> = 31) <3.5 ulcers per foot per 10 years: 36% of ulcers ( <i>n</i> = 114), 63% of participants ( <i>n</i> = 52)	% of participants non-adherent to footwear: ≥3.5 ulcers per foot per 10 years: 55 <3.5 ulcers per foot per 10 years: 35	Associated ( <i>p</i> = 0.037)
Waaijman et al. 2014 [22] * Prospective randomized controlled trial Period: 2007–2010 Location: the Netherlands (multicenter)	N: 171 Male: 82.5% Age: 63.3 ± 10.1 years Type 2: 71.3% Neuropathy: 100% Risk classification: IWGDF 3: 100%	QUIPS: L-M-M-L-L-L 21-item score: 12/17	At 18 months: Plantar ulcers: 42% ( <i>n</i> = 71)  At 18 months: Ulcers from unrecognized trauma: 24% ( <i>n</i> = 41)	% adherence (7-day period < 3 months after baseline): Plantar ulcers: 73.1 ± 24.7 No plantar ulcers: 72.7 ± 24.1  % adherence: Ulcers from unrecognized trauma: 72.2 ± 26.2 No ulcers from unrecognized trauma: 73.1 ± 23.7	Not associated (OR: 1.00, 95% CI: (0.99; 1.01), <i>p</i> = 0.989)  Not associated (OR: 1.00, 95% CI: (0.98; 1.01), <i>p</i> = 0.823)

Results expressed as mean ± standard deviation or median (quartile 1; quartile 3). Abbreviations: N = number of participants, type 2 = type 2 diabetes, CI = 95% confidence interval, OR = odds ratio. Quips domains: (1) Study participation, (2) Study attrition, (3) Prognostic factor measurement, (4) Outcome measurement, (5) Study confounding, (6) Statistical analysis and reporting. L = low, M = moderate and H = high risk of bias. \* Waaijman et al. 2014, plantar ulcers = any plantar ulcer; ulcers from unrecognized trauma = ulcer recurrence at previous ulcer location and not to be the result of acute trauma. A significance level of *p* < 0.10 was used.

**Table S7.** Cumulative plantar tissue stress - ulcer development.

Reference	Population	Risk of Bias	Ulcer Outcome	Factor + Outcomes	Conclusion
Waaijman et al. 2014 [22] * Prospective randomized controlled trial Period: 2007–2010 Location: the Netherlands (multicenter) Shoes: custom-made orthopedic footwear with or without pressure optimization	N: 171 Male: 82.5% Age: 63.3 ± 10.1 years Type 2: 71.3% Neuropathy: 100% Risk classification: IWGDF 3: 100%	QUIPS: L-M-M-L-L-L 21-item score: 12/17	At 18 months: Plantar ulcers: 42% ( <i>n</i> = 71)  At 18 months: Ulcers from unrecognized trauma: 24% ( <i>n</i> = 41)	Cumulative plantar tissue stress (7-day period <3 months after baseline) (MPa·s/day): Plantar ulcers: 715 ± 538 No plantar ulcers: 652 ± 436 % of participants with in-shoe PP at plantar foot <200 kPa and adherence >80%: Plantar ulcers: 9.0 No plantar ulcers: 10.2  Cumulative plantar tissue stress (MPa·s/day): Ulcers from unrecognized trauma: 423 ± 292 No ulcers from unrecognized trauma: 361 ± 279 % of participants with in-shoe PP at previous ulcer <200 kPa and adherence >80%: Ulcers from unrecognized trauma: 17.9	Not associated (OR: 1.00, 95% CI: (1.00; 1.00), <i>p</i> = 0.453)  Associated (OR: 0.47, 95% CI: (0.26; 0.85), <i>p</i> = 0.012)  Not associated (OR: 1.00, 95% CI: (1.00; 1.00), <i>p</i> = 0.162)  Associated (OR: 0.5, 95% CI: (0.28; 0.89), <i>p</i> = 0.019 (univariate), (OR:



No ulcers from unrecognized trauma: 27.3  
0.43, 95% CI: (0.20; 0.94),  $p = 0.033$   
(multivariate))

Results expressed as mean  $\pm$  standard deviation. Abbreviations: N = number of participants, type 2 = type 2 diabetes, MPa·s/day = MegaPascal times seconds per day, CI = 95% confidence interval, OR = odds ratio. Quips domains: (1) Study participation, (2) Study attrition, (3) Prognostic factor measurement, (4) Outcome measurement, (5) Study confounding, (6) Statistical analysis and reporting. L = low, M = moderate and H = high risk of bias. \* Waaijman et al. 2014, plantar ulcers = any plantar ulcer; ulcers from unrecognized trauma = ulcer recurrence at previous ulcer location and not to be the result of acute trauma. A significance level of  $p < 0.10$  was used.

**Table S8.** Plantar pressure - ulcer healing.

Reference	Population	Risk of bias	Ulcer outcome	Factor + outcomes	Conclusion
Armstrong et al. 1998 [1] Prospective cohort study Period: not presented Location: San Antonio, TX, USA (monocenter)	N: 25 Male: 68% Age: 52.4 $\pm$ 11.6 years Type 2: 84% Neuropathy: 100% Ulcer classification: Meggitt-Wagner grade 1 in depth: 100% Location: hallux: 4%, MTP1: 52%, MTP2: 12%, MTP3: 8%, MTP5: 12%, lateral midfoot: 4% and heel: 8% Area: 7.7 $\pm$ 4.0 cm <sup>2</sup>	QUIPS: H-L-L-H-L-L 21-item score: 11/17	Days until ulcer healing: >990 kPa: 53.4 $\pm$ 31.4 <990 kPa: 33.1 $\pm$ 13.0 Number of participants per group not presented	Barefoot cut-off PP > 990 kPa	Not associated ( $p = 0.05$ )
Van Netten et al. 2018 [21] Prospective cohort study Period: 2004–2013 Location: the Netherlands and Germany (multicenter) Device: removable knee-high or ankle-high offloading device	N: 31 Male: 81% Age: 60 $\pm$ 12.6 years Type 2: 94% Neuropathy: 100% Ulcer classification: 68% Texas 1A and 32% Texas 2A Location: hallux: 45%, MTP1: 26%, MTP2–5: 29% Area: 1.1 $\pm$ 0.9 cm <sup>2</sup>	QUIPS: L-L-L-M-M-M 21-item score: 13/17	Mean days until ulcer healing: 38.8 $\pm$ 21.3	Mean barefoot PP (kPa): 927 $\pm$ 143	Associated (95% CI: (0.1; 0.91), $p < 0.03$ )
Jarl et al. 2017 [7] Prospective cohort study Period: not presented Location: Uppsala, Sweden (monocenter) Device: non-removable ankle-high device	N: 7 Male: 100% Age: 63 (35–80) years Type 2: 100% Neuropathy: 100% Ulcer classification: Wagner grade 1: 57%, Wagner grade 2: 43% Location: MTP1: 57%, MTP3: 14%, MTP4: 14%, MTP5: 14% Area: 0.5 (0.2–2.0) cm <sup>2</sup>	QUIPS: H-L-M-M-H-H 21-item score: 12/17	At 12 weeks: Healed: 68% ( $n = 21$ )  Days until ulcer healing: 49 (8–160)	In-device PP (2 weeks after baseline) (kPa) Healed: 108 $\pm$ 56 Non-healed: 107 $\pm$ 57  In-device PTI (2 weeks after baseline) (kPa·s) Healed: 45 $\pm$ 29 Non-healed: 38 $\pm$ 17	Not associated (95% CI: (-45; 44), $p = 0.97$ , $d = 0.02$ )  Not associated (95% CI: (-28; 13), $p = 0.44$ , $d = 0.29$ )  Not associated ( $\rho = -0.600$ , $p = 0.208$ ) *

All plantar pressures are measured during baseline unless otherwise mentioned. Results expressed as mean  $\pm$  standard deviation or median (minimum–maximum). Abbreviations: N = number of participants, type 2 = type 2 diabetes, PP = peak pressure, PTI = peak pressure gradient, kPa = kilo Pascal, kPa·s = kilo Pascal times seconds,  $\rho$  = spearman's rho, 95% CI = confidence interval,  $d$  = effect size. Quips domains: (1) Study participation, (2) Study attrition, (3) Prognostic factor measurement, (4) Outcome measurement, (5) Study confounding, (6) Statistical analysis and reporting. L = low, M = moderate and H = high risk of bias. \* Jarl et al. 2017, analysis based on 6 participants using anonymized data provided by the author.

**Table S9.** Weight-bearing activity - ulcer healing.

Reference	Population	Risk of bias	Ulcer outcome	Factor + outcomes	Conclusion
Najafi et al. 2017 [15] Prospective randomized controlled trial Period: not presented Location: Doha, Qatar and AZ, USA (multicenter)	N: 49 Male: 92% Age: 53.7 ± 7.7 years Type 2: not presented Neuropathy: 100% Ulcer classification: noninfected, nonischemic, plantar neuropathic ulcers Location: not presented Area: 8.14 (0.16–39.0) cm <sup>2</sup>	QUIPS: H-M-M-L-H-H 21-item score: 12/17	At 12 weeks: Healed: 51% ( <i>n</i> = 22) *	Steps per day (baseline): Healed: 5304 ± 3567 Non-healed: 4312 ± 2658	Not associated ( <i>p</i> = 0.398)
				Steps per day (last visit or week before healing): Healed: 2595 ± 2056 Non-healed: 5586 ± 3186	Not associated ( <i>p</i> = 0.104)
				Standing % of 24 hours (baseline): Healed: 9.8 ± 5.3 Non-healed: 11.2 ± 6.7	Not associated ( <i>p</i> = 0.518)
				Standing % of 24 hours (last visit or week before healing): Healed: 5.7 ± 4.0 Non-healed: 11.4 ± 3.9	Associated (OR: 0.663, <i>p</i> = 0.013)
Van Netten et al. 2018 [21] Prospective cohort study Period: 2004–2013 Location: the Netherlands and Germany (multicenter)	N: 31 Male: 81% Age: 60 ± 12.6 years Type 2: 94% Neuropathy: 100% Ulcer classification: 68% Texas 1A and 32% Texas 2A Location: hallux: 45%, MTP1: 26%, MTP2–5: 29% Area: 1.1 ± 0.9 cm <sup>2</sup>	QUIPS: L-L-L-M-M-M 21-item score: 13/17	At 12 weeks: Healed: 68% ( <i>n</i> = 21)	Steps per day (2 weeks after baseline): Healed: 7222 ± 3272 Non-healed: 9706 ± 6520	Not associated (95% CI: (-541; 3023), <i>p</i> = 0.26, <i>d</i> = 0.48)

Results expressed as mean ± standard deviation. Abbreviations: N = number of participants, type 2 = type 2 diabetes, CI = 95% confidence interval, OR = odds ratio, *d* = effect size. Quips domains: (1) Study participation, (2) Study attrition, (3) Prognostic factor measurement, (4) Outcome measurement, (5) Study confounding, (6) Statistical analysis and reporting. L = low, M = moderate and H = high risk of bias. \* Najafi et al. 2017, 6 participants were excluded due to development of infection, surgical closure of ulcer and missed follow-up appointments during follow-up.

**Table S10.** Device adherence - ulcer healing.

Reference	Population	Risk of bias	Ulcer outcome	Factor + outcomes	Conclusion
Crews et al. 2016 [5] Prospective cohort study Period: 2008–2012 Location: UK and USA (multicenter)	N: 79 Male: 84% Age: 56.5 ± 9.6 years Type 2: 100% Neuropathy: not presented Ulcer classification: Texas 1A: 72%, Texas 1B: 12%, Texas 2A: 15%, Texas 2B: 1% Location: not presented Area: 23.0 ± 28.8 cm <sup>2</sup>	QUIPS: M-L-L-M-M-M 21-item score: 10/17	At 6 weeks: Healed: 24% ( <i>n</i> = 19)	% of activity for which off-loading device worn: Healed: 57 ± 24 Non-healed: 59 ± 22	No association ( <i>r</i> = -0.043, <i>p</i> = 0.705)
				Total adherent activity hours over 6 weeks: Healed: 8126 ± 8161 Non-healed: 8216 ± 5566	No association ( <i>r</i> = -0.006, <i>p</i> = 0.957)
				Mean % of activity for which off-loading device worn: 59 ± 22	Associated ( <i>β</i> = -0.16, <i>p</i> = 0.038)

Results expressed as mean ± standard deviation. Abbreviations: N = number of participants, type 2 = type 2 diabetes, *r* = Pearson correlation, *β* = standardized coefficient: *β*. Quips domains: (1) Study participation, (2) Study attrition, (3) Prognostic factor measurement, (4) Outcome measurement, (5) Study confounding, (6) Statistical analysis and reporting. L = low, M = moderate and H = high risk of bias.

**Table S11.** Cumulative plantar tissue stress - ulcer healing.

Reference	Population	Risk of Bias	Ulcer Outcome	Factor + Outcomes	Conclusion
Van Netten et al. 2018 [21] Prospective cohort study Period: 2004–2013 Location: the Netherlands and Germany (multicenter) Device: removable knee-high or ankle-high offloading device	N: 31 Male: 81% Age: 60 ± 12.6 years Type 2: 94% Neuropathy: 100% Ulcer classification: 68% Texas 1A and 32% Texas 2A Location: hallux: 45%, MTP1: 26%, MTP2–5: 29% Area: 1.1 ± 0.9 cm²	QUIPS: L-L-L-M-M-M 21-item score: 13/17	At 12 weeks: Healed: 68% ( <i>n</i> = 21)	Cumulative plantar tissue stress (2 weeks after baseline) (MPa·s/day) Healed: 155 ± 131 Non-healed: 207 ± 215	Not associated (95% CI: (-75; 179), <i>p</i> = 0.71, <i>d</i> = 0.29)
	At 12 weeks, in the adherent group * ( <i>n</i> = 27): ≥75% ulcer area reduction at 4 weeks: 70% ( <i>n</i> = 19) <75% ulcer area reduction at 4 weeks: 30% ( <i>n</i> = 8)		Cumulative plantar tissue stress (2 weeks after baseline) (MPa·s/day) ≥75% ulcer area reduction at 4 weeks: 140 ± 137 <75% ulcer area reduction at 4 weeks: 275 ± 209	Not associated (95% CI: (-5; 275), <i>p</i> = 0.09, <i>d</i> = 0.76)	

Results expressed as mean ± standard deviation. Abbreviations: *N* = number of participants, type 2 = type 2 diabetes, MPa s/day = Mega Pascal times seconds per day, *d* = effect size, CI = 95% confidence interval, OR = odds ratio. Quips domains: (1) Study participation, (2) Study attrition, (3) Prognostic factor measurement, (4) Outcome measurement, (5) Study confounding, (6) Statistical analysis and reporting. L = low, M = moderate and H = high risk of bias. \* Patients were classified as adherent when they self-reported to have worn their device >50% of the time while being inside and outside the house at ≥80% of their visits.

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