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Custom-made footwear designed for indoor use increases short-term and long-term adherence in people with diabetes at high ulcer risk

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ABSTRACT

Introduction To explore changes in footwear adherence following provision of custom-made indoor footwear in people with diabetes at high risk for plantar foot ulceration and in possession of regular custom-made footwear.

Research design and methods Adherence indoors and outdoors was assessed objectively as percentage of steps custom-made footwear was worn, at baseline (in regular custom-made footwear), and at 1 and 12 months after providing custom-made indoor footwear (in both indoor and regular footwear). Primary group: participants with low (<80%) baseline indoor adherence; secondary group: participants with high (≥80%) baseline indoor adherence. Peak plantar pressures of the indoor footwear were compared with the regular custom-made footwear. Footwear usability was evaluated at 3 months via a questionnaire. At 12 months, ulcer recurrence was assessed through participant/prescriber reporting.

Results Of 31 participants, 23 had low baseline indoor adherence (<80%). Overall adherence in this group increased statistically significant from median 65% (IQR: 56%–72%) at baseline to 77% (60%–89%) at 1 month (p=0.002) and 87% (60%–93%) at 12 months (p<0.001). This was due to a significant increase in adherence indoors: baseline: 48% (21%–63%); 1 month: 71% (50%–83%) (p=0.001); and 12 months: 77% (40%–91%) (p<0.001). Mean peak plantar pressures were comparable between the indoor and regular custom-made footwear. Participants were positive about usability. One-year ulcer recurrence rate was 26%.

Conclusions Footwear adherence increased in the short-term and long-term after provision of custom-made indoor footwear in people at high risk of diabetic foot ulceration with low baseline adherence, because they actively wore their newly provided indoor footwear inside their house. Footwear adherence may be helped by using both regular and indoor custom-made footwear in clinical practice; the effect on ulcer recurrence should be investigated in future trials.

Significance of this study

What is already known about this subject?

- Custom-made footwear is effective in ulcer prevention, but adherence is low indoors.

What are the new findings?

- Footwear adherence increased significantly in short-term and long-term after provision of custom-made indoor footwear in low-adherent participants.
- Footwear adherence remained high in high-adherent participants, with substantial use of the indoor footwear.
- Participants were generally satisfied with their custom-made indoor footwear, and scored most usability aspects positively.
- One-year ulcer recurrence rate was 26%.

How might these results change the focus of research or clinical practice?

- A combination of regular and indoor custom-made footwear is a useful intervention to increase adherence, and its implementation is recommended.

INTRODUCTION

Foot ulceration affects up to 30% of all people with diabetes in their lifetime and places a high burden on patients and carers as well as the healthcare system.[1] Once a foot ulcer has healed, recurrence within 1 year is around 40% and 60% within 3 years.[1] Due to this high risk of foot ulceration and its recurrence, its prevention is of fundamental importance.

Custom-made footwear is an effective intervention to help prevent foot ulceration[2 3] and is recommended in international guidelines.[4] The aim of such footwear is to reduce ulcer risk by redistributing and lowering mechanical stress at high-risk regions and providing a proper fit.[4] For footwear to achieve this, it needs to be worn.[5 6] However, adherence to wearing custom-made footwear is a challenge in people with diabetes at high ulcer risk, and they frequently wear footwear that is not protective or go barefoot (or in socks only) when weight-bearing.[4 5 7 8] Adherence is particularly low indoors, while approximately 60% of their daily steps are taken indoors.[9–11]

Interventions to specifically increase footwear adherence indoors are needed for this high-risk population.[5]

Research on adherence-increasing interventions, however, is limited; a recent systematic review found only one study that attempted to increase footwear adherence by using motivational interviewing.[12] This resulted in some improvement in footwear adherence 1 week after motivational interviewing, but a return of adherence to baseline levels after 3 months, with especially low adherence indoors.[9] Participants provided various reasons for their low indoor adherence, such as the weight of the footwear, difficulties with donning and doffing and difficulties moving around inside the house with their custom-made footwear.[9] Custom-made footwear specifically designed for indoor use might overcome these drawbacks and improve adherence.

We developed custom-made indoor footwear based on an evaluation of needs and preferences of people with diabetes and on a set of design rules such footwear should fulfil.[13] The most important was similar offloading efficacy compared with a person's regular custom-made footwear,[13] because indoor footwear may improve adherence by increasing wearing time indoors andcan replace time that regular custom-made footwear would otherwise be worn. We aimed to explore the short-term and long-term changes in footwear adherence following the provision of such custom-made indoor footwear in people with diabetes at high risk of foot ulceration and regular custom-made footwear.

RESEARCH DESIGNS AND METHODS

Study design and setting

A prospective non-controlled intervention study (pre–post design) in three multidisciplinary diabetic foot outpatient clinics.

Participants

Inclusion criteria were: type 1 or 2 diabetes mellitus; moderate to high risk for foot ulceration (International Working Group on the Diabetic Foot risk 2 or 3)[4]; and in possession of custom-made footwear (ie, custom-made insoles worn in custom-made footwear). Exclusion criteria were: presence of a foot ulcer; Charcot foot deformation or active Charcot's neuroarthropathy; amputation at or beyond the tarsometatarsal level; necessity to wear high-cut footwear (midtibia level or higher) at all times; and inability to walk unaided. Participants who took part in a preceding survey to assess needs and expectations regarding custom-made indoor footwear and expressed a need for such footwear were invited.[13] Written informed consent was obtained from all participants prior to inclusion.

Custom-made footwear

Prior to the study, all participants possessed custom-made footwear that was prescribed by a rehabilitation medicine specialist and manufactured by a certified pedorthist from each of the three participating multidisciplinary clinics. The footwear consisted of custom-made insoles worn in custom-made shoes, both handmade from a positive last of the foot. The shoe had rocker profile outsoles and multidensity insoles with pressure relieving elements.[14] This custom-made footwear is from here onwards referred to as 'regular footwear'.

Custom-made indoor footwear

During the study, participants were provided with custom-made footwear specifically intended for indoor use (referred to as 'indoor footwear' from here onwards), in addition to their regular custom-made footwear. To ensure the same biomechanical offloading capacity as the regular footwear, the indoor footwear (online supplemental figure S1) was built on the same shoe last, was ankle-high (ie, above ankle but below midtibia level) and was fitted with a custom-made insole similar to the insole used in the regular footwear.[13] This similarity in offloading capacity was the key characteristic as determined in our pilot study,[13] because people may replace wearing of their regular footwear inside their house with wearing the indoor footwear. To maintain an optimal biomechanical environment, similarity in offloading between regular and indoor footwear is important, and this was objectively assessed (see sections '*Procedures*' and '*In-shoe plantar pressure measurements*' for more information). To facilitate usability, the shoe outsole was a lightweight material, the vamp was made of either microfiber (online supplemental figure S1 Type A), or felt (online supplemental figure S1 Type B) and held together with a combination of leather, Velcro fastener and a zipper. Prior to the start of the study, participants were informed that the indoor footwear would be provided free of charge.

Procedures

On study entry, demographic and disease-related data were collected. Loss of protective sensation was assessed with a 10 g Semmes-Weinstein monofilament,[15] foot amputations were documented by clinical assessment, and photographs of the feet were taken. Baseline adherence was determined by measuring step count with an activity monitor at the ankle and footwear use with a temperature sensor (see '*Adherence*' section for details).

After this baseline visit, the indoor footwear was manufactured, and on its delivery, in-shoe plantar pressures were measured in both the participants' regular and indoor footwear (see '*In-shoe plantar pressure measurements*' section for details). If necessary, the footwear was modified until peak pressures were similar between the two footwear types.[4 6 16] One month after provision, adherence was again determined, now in the combination of regular and indoor footwear. At 3 months, a questionnaire was sent to the participants to evaluate: (1) usability, (2) satisfaction and (3) appearance of the indoor footwear and (4) the willingness to pay for the indoor footwear if prescribed in clinical practice. The questionnaire was based on the Monitor Orthopedic Shoes[17] and

consisted of questions scored on a 5-point Likert scale. The response options were combined to three categories: 'not or hardly present', 'neutral' and '(very much) present'. At 12 months, adherence was again determined in the combination of regular and indoor footwear. Any ulcer (recurrence) that had occurred in the previous 12 months was identified based on participant or pedorthist reports.

Adherence

Footwear adherence was determined by combining seven consecutive days of footwear use and daily step count measurements. Footwear use was measured with a small temperature-based sensor (@monitor, Department of Medical Technology and Innovation, Academic Medical Center, Amsterdam, The Netherlands), placed inside the custom-made footwear and recording temperature at 1 min intervals. The one or two pairs of footwear that were most frequently used, or three after provision of the indoor footwear, were provided with the @monitor. Simultaneously, daily step count was recorded with an activity monitor strapped above the ankle (StepWatch, Orthocare Innovations LLC, Oklahoma, USA). Participants were instructed to wear the StepWatch at all times, except when showering or bathing. Time spent outdoors, cycling and not wearing the StepWatch were logged by the participants in a report form.

Footwear use and daily step count were obtained for each measurement day and analyzed with custom-built software in Matlab R2018a (MathWorks, Natick, Massachusetts, USA).[10] Only valid recordings (ie, a minimum of 4 days of combined step count and footwear use measured, including 1 weekend day) were included in analyses.[18 19] Barefoot walking or walking in non-prescribed footwear was assumed when the StepWatch showed activity and the @monitor did not show footwear usage. The daily activity log was used to differentiate between indoor and outdoor adherence. Adherence was defined as the percentage of steps while wearing prescribed footwear and calculated as the ratio between the cumulative number of steps with prescribed footwear worn and the total number of steps taken. 'Low indoor adherence' was defined as <80% of the total steps indoors taken in prescribed footwear.[6]

In-shoe plantar pressure measurements

In-shoe peak plantar pressures were measured dynamically with the Pedar-X in-shoe pressure measurement system (Novel GmbH, Munich, Germany) at a 50 Hz sampling frequency. To increase generalizability, participants were asked to walk at a comfortable speed over a flat surfaced walkway. The first and last step of each walk were discarded. Plantar pressure data were collected over a minimum of 12 midgait steps per foot per condition, as determined to be valid and reliable.[20] Pressures were analyzed with Novel multimask software (V.13.3.65). The mean peak pressures at eight anatomical foot regions were calculated for the left and right foot separately: the toes (hallux, dig 2–3 and dig 4–5), forefoot (metatarsal head 1, metatarsal head 2–3 and metatarsal head 4–5), midfoot and heel.

Statistical analysis

Patient characteristics, adherence, daily step count, total wearing time and in-shoe peak plantar pressures were summarized using descriptive statistics. Separate analyses were undertaken for participants with low indoor adherence (<80%, primary group) and high indoor adherence (≥80%) at baseline. Independent samples t-tests and Fisher's exact tests were used to compare patient characteristics between low-adherence and high-adherence groups. Wilcoxon signed rank test was used to compare adherence, step count and wearing time between both follow-up moments and baseline. Paired sample t-test was used to compare in-shoe peak plantar pressures between indoor and regular custom-made footwear for the eight anatomical regions of both the left and right foot. A Bonferroni-corrected significance level of $p<0.025$ (0.05/2) was used for adherence and wearing time, as two primary analyses were done, and $p<0.004$ (0.05/12) for peak plantar pressures. Wilcoxon effect sizes (r) were calculated for adherence and wearing time as follows: $r=Z/\sqrt{(N)}$. Statistical analyses were performed using SPSS V.26.0 (SPSS Inc). In case of missing adherence data at baseline, adherence was imputed using missing value analysis regression in SPSS, with wearing time as predictor. First observation carried backward was used to impute missing adherence data at 1 month and last observation carried forward for missing adherence data at 12 months follow-up. Data were not imputed in case of death.

RESULTS

Participants

Thirty-four participants completed baseline measurements; three dropped out during follow-up (figure 1). Twenty-three participants had low indoor adherence at baseline, and eight had high adherence (table 1). Of the 31 analyzed participants, 13 were female (42%), mean (SD) age was 69.3 (9.9) years, and 24 had type 2 diabetes (77%), with no difference between low-adherence and high-adherence groups (table 1).

Missing data

Adherence data were missing for three participants at baseline (equipment failure), three at 1 month (equipment failure, hospitalization and missed visit) and eight at 12 months follow-up (two equipment failure, one untraceable, and five missed visit). Analyses on the imputed dataset and on available cases provided similar results; we used the imputed dataset for reporting.

Footwear adherence, wearing time, and step count

In participants with low baseline adherence, overall adherence increased significantly from baseline (65%) to 1 month (77%; p=0.002; r=0.66) and from baseline to 12 months (87%; p<0.001; r=0.74; table 2). Adherence indoors increased significantly from 48% to 71%

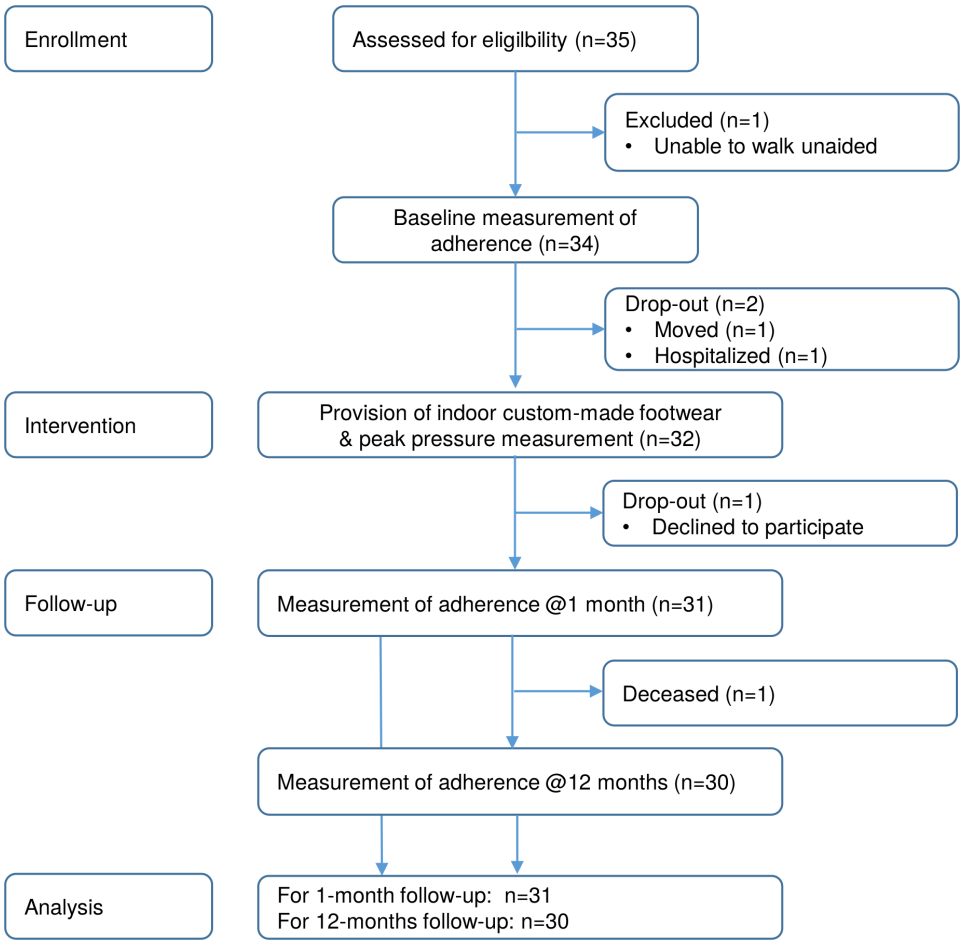

Figure 1 Flow diagram summarizing participants included and excluded from analysis.

(p=0.001; r=0.74) and 77% (p<0.001; r=0.78), respectively. Adherence outdoors was high at baseline (94%) and improved non-significantly to 98% and 99%, respectively (table 2).

Ten of 23 participants (44%) with low baseline adherence improved to high adherence (>80% of steps) at 1 month and 12 participants (55%) at 12 months. Similar to adherence, time that custom-made footwear (indoor

Table 1 Participant characteristics

	Baseline indoor adherence low (n=23)	Baseline indoor adherence high (n=8)	P value	All participants (n=31)
Age (years)	68.3±11.2	72.1±4.2	0.357	69.3±9.9
Female gender	39(9)	50(4)	0.689	42(13)
BMI (kg/m^2)	30±7	32±8	0.614	31±7
Type 2 diabetes	78(18)	75(6)	1.0	77(24)
Diabetes duration (years)*	19.5±15.7	19.5±10.2	0.997	19.5±14.5
LOPS, based on abnormal monofilament perception	100(23)	100(8)	–	100(31)
Amputation†	22 (5)	25 (2)	1.0	23 (7)
Digiti	(3)	(2)		(5)
Ray/Forefoot	(2)	0		(2)

Data are expressed as mean±SD, or % (n). No significant differences were found between the groups baseline indoor adherence 'low' and 'high'.
*Diabetes duration was available from n=27.
†Amputation up to tarsometatarsal level.
BMI, body mass index; LOPS, loss of protective sensation.

Table 2 Adherence in % of steps taken in prescribed footwear, wearing time indoor, and regular footwear in hours a day, and indoor footwear relative to total wearing time

	Baseline indoor adherence low (n=23)			Baseline indoor adherence high (n=8)			All participants (n=31)		
	Baseline	**1 month**	**12 months**	**Baseline**	**1 month**	**12 months**	**Baseline**	**1 month**	**12 months**
	Adherence								
Overall	65 (56–72)	77 (60–89) p=0.002* *r*=0.66‡	87 (60–93) p<0.001* *r*=0.74	96 (93–97)	94 (91–96) p=0.306 *r*=0.36	95 (79–97) p=0.203 *r*=0.45	71 (60–90)	83 (67–94) p=0.006* *r*=0.49	90 (69–95) p=0.003* *r*=0.54
Indoor	48 (21–63)	71 (50–83) p=0.001* *r*=0.74	77 (40–91) p<0.001* *r*=0.78	94 (91–95)	93 (89–94) p=0.268 *r*=0.41	93 (93–96) p=0.496 *r*=0.26	57 (34–87)	77 (52–93) p=0.002* *r*=0.62	84 (55–93) p=0.001* *r*=0.65
Outdoor	94 (85–98)	98 (92–100) p=0.135 *r*=0.34	99 (94–100) p=0.028 *r*=0.52	99 (99–100)	100 (100–100) p=0.034* *r*=0.80	100 (100–100) p=0.034* *r*=0.80	96 (86–99)	100 (100–100) p=0.059 *r*=0.37	100 (100–100) p=0.010* *r*=0.51
	Wearing time indoor and regular footwear								
Overall	8.6 (4.9–9.8)	9.3 (7.4–12.6) p=0.001* *r*=0.68	12.0 (8.1–14.2) p=002* *r*=0.75	14.7 (14.2–15.4)	14.6 (13.1–15.1) p=0.309 *r*=0.39	17.9 (10.5–15.4) p=0.735 *r*=0.13	9.4 (6.5–12.2)	11.5 (8.2–4.4) p=0.004* *r*=0.54	12.9 (8.7–15.1) p=0.005* *r*=0.57
	Wearing time indoor footwear relative to total wearing time								
Indoor footwear	NA†	4.7 (2.9–7.1)	5.7 (2.0–7.1) p=0.796 *r*=0.07	NA	10.3 (6.5–11.9)	3.9 (3.5–10.4) p=0.173 *r*=0.56	NA	5.7 (2.9–7.8)	5.6 (2.6–7.3) p=0.548 *r*=0.13
Regular footwear	8.6 (4.9–9.8)	4.5 (3.3–6.6)	5.4 (3.1–9.0) p=0.796 *r*=0.07	14.7 (14.2–15.4)	4.7 (2.7–8.2)	5.7 (3.2–11.9) p=0.173 *r*=0.56	9.4 (6.5–12.2)	4.6 (3.2–7.4)	5.6 (3.3–10.7) p=0.249 *r*=0.25

Data are expressed as median (IQR).
*Significantly different between baseline and follow-up (Bonferroni-corrected level of significance: p<0.025 (0.05/2)).
†NA=not applicable; because the indoor footwear was provided only after baseline measurement. Please note that values are median; hours of indoor and regular footwear cannot be added up.
‡*r=Wilcoxon effect size*

and regular) was worn increased significantly from 8.6 hours/day to 9.3 hours/day (p=0.0014; r=0.68) and 12.0 hours/day (p=0.002; r=0.75; table 2), respectively. Wearing time at 1 and 12 months was evenly distributed between indoor and regular footwear (table 2).

In participants with high indoor adherence at baseline, both adherence (table 2) and wearing time (table 2) remained high. They wore the indoor footwear 10.3 hours/day at 1 month and 3.9 hours/day at 12 months.

All participants took more steps indoors compared with outdoors and had a non-significantly lower daily step count during follow-up compared with baseline (table 3). In participants with low baseline adherence, 59% of indoor steps were in the indoor footwear at 1 month and 45% at 12 months. In participants with high adherence at baseline, this was 81% and 45%, respectively. The indoor footwear was hardly used outdoors (range: 0%–2%).

Peak plantar pressures

Peak plantar pressures in all regions of the indoor footwear were comparable with the regular footwear (table 4). Peak pressures >200 kPa were less frequently present in indoor footwear (table 4).

Usability of indoor footwear

Response rate for the usability questionnaire was 90% (n=28). Most responders (79%) were satisfied or very satisfied with the indoor footwear (table 5), and 68% felt that it met their expectations. The indoor footwear was considered appealing by 43% of the respondents. All but one of the respondents reported negative usability aspects 'difficult to don and doff', 'too heavy', 'too tight fit' and 'skin irritation' as neutral or not or hardly present (table 5). The largest group of responders (36%) were willing to pay between €0 and €50 for the indoor footwear and 32% between €50 and €100.

Ulcer recurrence

Eight of the 31 participants (26%) developed a recurrent ulcer during follow-up, of which four had low indoor adherence at baseline. Seven out of eight ulcers were plantar, of which five in the forefoot and two locations unknown; one ulcer was dorsal, caused by skin getting caught in the zipper of the indoor footwear.

DISCUSSION

We assessed changes in footwear adherence after provision of custom-made indoor footwear in people with diabetes at high risk of foot ulceration and already in possession of regular custom-made footwear. People with low baseline indoor adherence significantly increased their adherence in the short-term and long-term after provision of indoor footwear, predominantly as a result of increasing their indoor adherence, as well as wearing time. Adherence remained high in people with high baseline indoor adherence; they wore their indoor footwear for substantial amounts of time in the short term and long term. Ulcer recurrence in 12 months was 26%, with mostly plantar ulcers. The indoor footwear had similar offloading capacity as regular custom-made footwear, and almost all participants were satisfied with the indoor footwear and were neutral or positive about usability aspects. Custom-made indoor footwear in addition to regular custom-made footwear therefore seems a useful intervention to improve adherence to wearing prescribed footwear in people with diabetes at high risk of foot ulceration.

Adherence strongly improved both in the short term and long term from additionally providing a pair of custom-made indoor shoes. As expected, indoor adherence improved the most, because the intervention specifically targets indoor adherence, and because indoor adherence was lowest at baseline and therefore had most potential to increase. People with low adherence at baseline (ie, <80% of steps indoors in protective footwear) showed absolute 23% and 29% improvements in adherence in the short term and long term, respectively. At 12 months, 55% of this group was highly adherent. Outdoor adherence was already high at baseline in this group,and remained high over time, showing that footwear adherence is not so much an issue outdoors. However, participants were clearly more active inside their homes compared with outside, even more than found in previous studies.[9–11] This again stresses the importance of an intervention specifically targeting indoor adherence. In line with increased adherence, wearing time also increased. This suggests that the higher percentage of steps taken in protective footwear was the result of an increase in hours the footwear was worn.

Adherence and wearing time in participants with high baseline adherence remained high over time. Given the high baseline adherence of 96%, little opportunity for increased adherence was possible for this group. Important, however, was that most steps indoors were taken in the indoor footwear at 1 month and still almost half at 12 months. This indicates that people with high adherence also benefit from the provision of indoor footwear and suggests that its provision should not be limited to those with low indoor adherence.

Almost all participants were satisfied with their indoor footwear, and most scored positive on usability aspects. Earlier research showed that difficulties with donning and doffing, as well as the weight of the footwear, are reasons for low indoor adherence.[9] These usability aspects were considered in the indoor footwear design. The positive usability scores, in combination with the increased adherence, suggest a successful design of the indoor footwear for most people.

The ulcer recurrence rate was 26% in 12 months, lower than found in a review[1] but still considerable given the increase in adherence. Although high footwear adherence combined with pressure-reducing footwear reduces the risk for plantar foot ulcer recurrence,[6] it does not eliminate risk completely. The recurrence rate found in our study may be explained by the improved but still

Table 3 Daily step count at various time points

	Baseline indoor adherence low (n=23)			Baseline indoor adherence high (n=8)			All participants (n=31)		
	Baseline	1 month	12 months	Baseline	1 month	12 months	Baseline	1 month	12 months
Overall	5580 (3562–7187)	3722 (2726–5797) p=0.355	3921 (2179–6864) p=0.179	5976 (3769–6857)	3321 (2135–5025) p=0.176	3591 (2145–6504) p=0.249	5580 (3145–7016)	3522 (2509–5567) p=0.124	3790 (2206–6410) p=0.101
Indoor	3202 (2405–4887)	2694 (2156–4326) p=0.744	2307 (1721–2966) p=0.88	4147 (2685–4759)	2904 (1605–4476) p=0.398	2050 (1518–6463) p=0.893	3345 (2418–4809)	2799 (2056–4342) p=0.677	2050 (1751–3303) p=0.204
Outdoor	1744 (1084–3332)	835 (517–2467) p=0.286	1375 (339–2536) p=0.650	1591 (929–2440)	859 (418–1122) p=0.091	716 (305–1761) p=0.080	1593 (831–2527)	847 (492–1447) p=0.074	1326 (353–2262) p=0.167
Relative use of indoor footwear indoors	NA*	59 (29–74)	45 (15–71)	NA	81 (43–86)	45 (20–65)	NA	62 (37–76)	45 (20–66)
Relative use of indoor footwear outdoors	NA	2 (0–10)	0 (0–1)	NA	1 (0–6)	0 (0–39)	NA	1 (0–9)	0 (0–1)

Data are expressed as median (IQR) or %.
*NA=not applicable; because the indoor footwear was provided only after baseline measurement. No significant differences were found between baseline and follow-up (p<0.05).

Table 4 Peak plantar pressures for indoor and regular custom-made footwear

		Indoor footwear*	Regular footwear*	Mean difference (95% CI)†‡	% difference	P value
Hallux	Left	121±46	122±53	−1 (−12 to 11)	−1	0.908
	Right	124±47	128±66	−4 (−18 to 9)	−3	0.525
MTH1	Left	141±40	145±60	−4 (−21 to 14)	−3	0.653
	Right	146±40	153±72	−8 (−28 to 13)	−5	0.467
MTH2-3	Left	145±36	151±56	−6 (−22 to 10)	−4	0.460
	Right	157±43	157±52	−1(−13 to 12)	−1	0.916
MTH4-5	Left	121±39	124±45	−3 (−15 to 9)	−2	0.599
	Right	124±48	123±52	0 (−9 to 10)	0	0.972
Midfoot	Left	117±38	115±35	2 (−8 to 12)	2	0.634
	Right	112±29	115±36	−4 (−12 to 4)	−3	0.343
Heel	Left	187±52	201±76	−14 (−33 to 3)	−7	0.112
	Right	185±58	209±69	−24 (−47 to −1)	−10	0.046

*Data are provided as mean±SD kPa.
†Mean difference is peak pressure in indoor footwear minus custom-made footwear; a negative score means lower pressures in the indoor footwear.
‡No significant differences were found between indoor and regular footwear (Bonferroni-corrected level of significance: p<0.004 (0.05/12)).
MTH, metatarsal head.

not optimal adherence in some cases. For people at high risk, every step without protection may be one too much. Second, the target peak pressure of 200 kPa[6 21 22] used in the design of the indoor footwear may still be too high for some people, for instance in case of ample weight-bearing activity, resulting in excessive plantar cumulative tissue stress.[23 24] Although our results suggest that indoor footwear potentially may help in ulcer prevention, its effectiveness should be assessed in a randomized controlled trial (RCT) with ulcer recurrence as a primary outcome. However, as indoor footwear in itself may not be enough to remove all barriers in ulcer prevention, this intervention should preferably be combined with additional preventative interventions as part of an RCT using a personalized treatment approach for ulcer prevention.[25]

Table 5 Satisfaction and usability characteristics of participants' indoor footwear

Overall satisfaction	(Very) unsatisfied	Neutral	(Very) satisfied
	7 (2)	14 (4)	79 (22)
Positive usability characteristics	Not or hardly present	Neutral	(Very much) present
Good durability	–	50 (14)	50 (14)
Easy maintenance	10 (3)	29 (8)	61 (17)
Appealing footwear	–	57 (16)	43 (12)
Negative usability characteristics	Not or hardly present	Neutral	(Very much) present
Too much sweating*	85 (22)	15 (4)	–
Too heavy*	88 (23)	8 (2)	4 (1)
Cold feet†	89 (24)	11 (3)	–
Difficult to donn and doff	89 (25)	7 (2)	4 (1)
Too tight fit†	93 (25)	4 (1)	4 (1)
Ulceration†	93 (25)	4 (1)	4 (1)
Skin irritation†	93 (25)	4 (1)	4 (1)

Data expressed as % (n) of responders.
*Missing data n=2.
†Missing data n=1.

A strength of the present study was the objective measurement of footwear adherence, as recommended for diabetic foot disease research.[26] While this might affect adherence due to participants' awareness of being monitored,[27] such an effect would be similar for baseline and follow-up measurements, and there is therefore no reason to assume that the improvement in adherence was caused by something other than the intervention. Another strength was that adherence was assessed in both the short term and the long term, providing a more valid and robust outcome. The lack of a control group not receiving indoor footwear or a control group with off-the-shelf footwear could be seen as a study limitation. However, we aimed to explore the effect of the intervention on adherence, for which a pre–post design is suitable. Nevertheless, we recommend to include a control group in future trials with this intervention. A limitation was how foot ulcer recurrence was assessed. Being a secondary outcome, full details and independent outcome assessment of ulcers were not obtained. While this limits interpretation regarding ulcer severity, the current finding of 26% ulcer recurrence is a useful indication of the potential effect of this single intervention on ulcer recurrence and can be used for power calculations to inform

future RCTs. Finally, we had to deal with missing data, with equipment failure one of the main causes. However, we estimate a limited effect of missing data, as we could use wearing time for imputation, which is strongly related to adherence,[10] and because the imputed data analysis showed similar results to analysis of the non-imputed data.

This is the first study that explored the effect of providing custom-made indoor footwear in addition to regular footwear on footwear adherence. Even though adherence was still low in some participants and many of them did not take every step indoors with the prescribed footwear, the results do suggest that the provision of indoor footwear in addition to regular footwear can be a useful intervention in daily practice for people with diabetes at high risk of ulceration. With costs being higher than participants are willing to pay, reimbursement is required.

CONCLUSIONS

Adherence to wearing custom-made footwear increased in the short term and long term after provision of custom-made indoor footwear with adequate offloading properties for people at high-risk of diabetic foot ulceration. This was because they wore their custom-made indoor footwear inside their house and positively assessed its usability. Due to the substantially improved adherence, the combination of wearing custom-made indoor and regular footwear produces a more continuous low-pressure environment for the foot at risk. Implementation of this intervention may have a positive effect on ulcer recurrence, but this should be investigated in future trials.

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Ethics approval This study involves human participants, but the Medical Ethics Review Committee of the Amsterdam University Medical Center waived the requirement for ethical review under the Medical Research Involving Human Subjects Act (WMO) (W17_405#17.474). Participants gave informed consent to participate in the study before taking part.

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