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The effectiveness of motivational interviewing on adherence to wearing orthopedic shoes in people with diabetes at low-to-high risk of foot ulceration: A multicenter cluster-randomized controlled trial

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ABSTRACT

Aim: To evaluate the effectiveness of motivational interviewing (MI) performed by MI-trained podiatrists in improving adherence to wearing orthopedic shoes in comparison to usual care in people with diabetes at low-to-high risk of ulceration.

Methods: People with diabetes with loss of protective sensation and/or peripheral artery disease, and with orthopedic shoes prescription were allocated to receive one MI-consultation by a podiatrist randomized to MI training (n = 53) or usual care only (n = 68). Adherence was measured as the percentage of steps taken while wearing orthopedic shoes, determined using an insole temperature microsensor and wrist-worn activity tracker during one week at 3 and 6 months.

Results: The proportion of participants ≥80 % adherent to wearing their orthopedic shoes was higher in the control group than in the MI-intervention group at 3 months (30.9 % versus 15.1 %; p = 0.044), and not significantly different at 6 months (22.1 % versus 13.2 %; p = 0.210). Average adherence was also higher in the control group than the intervention group at both 3 months (60.9 % versus 50.9 %; p = 0.029) and 6 months (59.9 % versus 49.5 %; p = 0.025).

Conclusions: One podiatrist-led MI-consultation in its current form did not result in higher adherence to wearing orthopedic shoes in people with diabetes 3 and 6 months after inclusion.

Trial registration: Netherlands Trial Register NL7710 (available on the International Clinical Trials Registry Platform).

1. Introduction

With a lifetime prevalence of 19–34 % foot ulceration is a common complication in people with diabetes mellitus [1,2]. Diabetic foot ulcers can lead to infection, hospitalization, and amputation [1] and are associated with immobility and reduced quality of life [3]. To prevent re-ulceration, self-management for early risk detection and protective footwear such as orthopedic shoes are considered essential [4–6]. People with diabetes who are adherent to these strategies have significantly better outcomes than those who are not [7]. However, research has shown that adherence to wearing orthopedic shoes is rather low, with only 46–49 % of people with diabetes wearing their orthopedic shoes ≥ 80 % of their daily total steps [5,8]. Since it's a challenge to achieve better adherence, new interventions are needed to improve adherence

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[9].

Previous studies have shown that communication with the healthcare provider is essential to influence someone's decision to use orthopedic shoes and is associated with increased long-term use of orthopedic shoes [10,11]. Regarding good communication, it is important to patients that they feel being listened to and that they are involved in the prescription process of orthopedic shoes, to be able to make their own choices during that process (i.e., establish a partnership) [10]. As such, it is thought that good communication can improve adherence to wearing orthopedic shoes [10,12].

Motivational interviewing (MI), defined as a collaborative, goal-oriented style of communication of the healthcare worker with particular attention to the language of change [13], may stimulate a satisfactory working alliance and, as a result, positively influence adherence. MI is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's reasons for change within an atmosphere of acceptance and compassion [14]. Recently, a small explorative study showed that MI had clinically relevant short-term positive effects on adherence to wearing orthopedic shoes in people with diabetes 1 week after the intervention [4]. However, adherence returned to baseline levels 3 months after the intervention. Besides, in this study MI was performed by investigators who had no direct clinical experience in treating people with diabetic foot problems.

Because podiatrists work at the frontline of diabetic foot care, MI may be an opportunity for podiatrists to increase adherence to recommended self-care behavior [15]. Previous research already showed that podiatrists can be trained to apply MI in daily clinical practice [16,17]. However, adequately powered randomized controlled trials (RCTs) with longer-term follow-ups (e.g. six months or more) are needed to establish the efficacy of MI in improving adherence to wearing orthopedic shoes [4,16,17]. Therefore, this RCT aimed to evaluate the effectiveness of MI performed by an MI-trained podiatrist, in improving objectively measured 3- and 6-months adherence to wearing orthopedic shoes and 1-year ulcer prevention in comparison to usual care in people with diabetes at low-to-high risk of foot ulceration. Additionally, the participants experiences on the use and usability of their orthopedic shoes and health-related quality of life (HRQoL) were assessed.

2. Methods

2.1. Study design

This study was designed as a multicenter, cluster-randomized controlled trial. The study was exempted from the requirement of full medical ethical approval by the CMO region Arnhem – Nijmegen (NL 68567.091.19). The CMO judged that the participants were not subjected to (such) actions or no (such) behavior was imposed on them to fall under the Dutch Medical Research Involving Human Subjects Act (WMO), and as such the study was exempt from full medical ethical approval under Dutch law. Subsequent ethical approval for the study protocol was obtained from the Ethical Committee of the BMS faculty of the University of Twente (190141). The protocol for this RCT has been published elsewhere [18]. All participants gave written informed consent before taking part in this study.

2.2. Study participants

People with diabetes, for whom foot care was reimbursed in the Dutch healthcare system, were recruited at different locations of Voetencentrum Wender and Voetmax Orthopedie, located in the east of the Netherlands. Inclusion criteria were: a clinical diagnosis of diabetes type 1 or 2; aged $\geq$ 18 years, classified with risk profiles 1–3 according to the International Working Group on Diabetic Foot (IWGDF) [19], and prescribed with orthopedic shoes. Exclusion criteria were having a foot ulcer, as a result of which no orthopedic shoes could be worn at the time of inclusion, active Charcot's neuro-arthropathy or foot infection, being unable to walk, or being unable to read and understand the study instructions.

2.3. Randomization

The randomization process is described in detail in our published protocol [18]. Randomization was performed at the level of the podiatrist, so that the background assignment of the participant's regular podiatrist (being trained in MI or not) determined the treatment allocation of the participants to either the intervention or control group. The randomization was done centrally by an independent researcher using https://www.sealedenvelope.com [18].

2.4. Interventions

Usual care consisted of: (a) foot screening and professional foot care by a podiatrist once every 1–12 months, depending on the IWGDF risk classification; (b) structured education about appropriate foot self-care for preventing a foot ulcer; (c) orthopedic shoes fitted by a pedorthist, if indicated based on foot condition and ulcer risk, as provided in standard clinical practice in the Netherlands in accordance with evidence-based guidelines [9].

The intervention consisted of usual care plus MI. A certified MI-trainer trained the podiatrists assigned to the MI-group in the principles of MI during a 3-day (21hrs) basic training [17]. After their basic MI-training the podiatrists were able to apply MI in daily clinical practice at a solid beginner level and did this significantly better than untrained podiatrists, as we have described in a previous publication [17]. During the MI-consultations the podiatrist focused on improving acceptance of and adherence to orthopedic shoes.

In both groups, all consultations with the podiatrist were planned as much as possible with the participant's regular podiatrist or with one of the other podiatrists belonging to the same randomized group as the regular podiatrist (being trained in MI or not) during the 12-month follow-up period.

2.5. Procedures and assessments

All participants were followed for 12 months. At inclusion, after providing informed consent and receiving their new pair of orthopedic shoes, the investigator embedded a validated temperature microsensor (Orthotimer®) in the custom-made insole of every pair of orthopedic shoes possessed and used at study entry (i.e. earlier prescriptions) or that was prescribed during follow up for determining wearing time of the orthopedic shoes. The sensor was placed in the medial arch of one of the shoe insoles, because of sufficient place in the insole, relatively low pressure from the foot, and its previous validation at this location [20]. Participants allocated to the intervention group had an extra consultation with an MI-trained podiatrist for a single MI-consultation. This consultation occurred around the time the participants received their orthopedic shoes.

During the 12-month follow-up period, the participants had, besides their regular consultations with their podiatrist and pedorthist, a consultation with one of the investigators at 3, 6, 9, and 12 months after inclusion. During these consultations, the temperature microsensors were read out with the Orthotimer® reading device. Additionally, the participants received a reliable wearable wrist activity monitor (Misfit Shine 2^{TM}) [21] at 3 and 6 months to continuously register their steps taken, and were instructed to wear this activity monitor for one whole week starting the day after the consultation (24 h per day).

Additionally, we assessed the proportion of participants (re-)experiencing ulceration based on self-report, asked during the consultations with the investigators, and clinical data, up to 1 year after inclusion. Clinical data (including notes and photos) from all participants were obtained from the digital patient file of the podiatrist. Besides, if the participant self-reported that they experienced an ulcer up to 1 year that

resulted in hospital treatment, the clinical data from the relevant hospital was obtained. For validation, we also checked if there was clinical hospital data available from 20 % of randomly chosen participants who self-reported that they experienced an ulcer during the 1-year follow-up, but did not indicate that they had been to a hospital for treatment. Only one participant was treated in the hospital while they indicated that this was not the case. In addition, the total number of ulcer-days from both the intervention and the control group were determined. An ulcer-day was defined as a day on which a participant had one or more foot wounds at one or both feet.

The participants were also asked to fill in the RAND-36 item Health Survey V2.0 (RAND-36 V2.0) at inclusion, 6 and 12 months, and the Monitor Orthopedic Shoes post-part (MOS) [22] at 6 and 12 months. The RAND-36 V2.0 is the validated Dutch version of the 36-item Short Form Health Survey (SF-36) and assesses experienced health status and health related-quality of life (HRQoL) [23,24]. The MOS post-part was designed to measure the use and the most relevant factors of usability of orthopedic shoes from a participant's perspective through multiple choice and visual analog scale (VAS) questions [22].

2.6. Outcomes

2.6.1. Primary outcome

In line with the IWGDF guidelines and previous studies, adherence was objectively measured [6,20,22,25]. The level of adherence to wearing orthopedic shoes was determined by the percentage of total steps taken during the two 1-week periods that the step counts were registered by the activity monitor and were calculated separately for these two measurements as follows:

$$\text{Week adherence} = \frac{\Sigma \text{stepswearing orthopaedic shoes in total week(n)}}{\Sigma \text{ steps in total week (n)}} * 100\%$$

Total steps wearing orthopedic shoes were calculated using the continuous log data from temperature microsensors fitted in the orthopedic shoes of all participants [18]. Total steps were calculated using data from activity monitors over the 1-week period [18]. The primary outcome for this study was the proportion of participants who sufficiently adhered to wearing their orthopedic shoes at 3 months (short-term) and 6 months (longer-term) after inclusion, defined as minimally 80 % of steps taken in their orthopedic shoes [5,8].

Raw data from the temperature microsensors were analyzed using the validated Groningen algorithm, version 2, to determine shoe use [20,26]. Wearing times of orthopedic shoes and daily step counts from the activity monitor were processed in MATLAB (The MathWorks Inc., Natick, MA, USA). Adherence to wearing orthopedic shoes was only calculated for participants if at least four complete days of step count recordings, including one weekend day, were available [8]. Data could be missing due to delayed sensor readings or drop-outs. Besides this data was considered invalid when data showed inactivity $\geq$ 3 h between 07.00 and 22.00 h. For the participants for whom it was not possible to calculate adherence due to missing or invalid data, adherence was imputed using single-imputation with linear regression with residual estimation adjustment based on the available data of the wearing time of their orthopedic shoes. However, missing or invalid activity data were not imputed and included in the analysis. The correlation between observed wearing time and adherence in the current sample was strong at $r = 0.65$ ($N = 85$) and 0.76 ($N = 80$) at 3 and 6 months after inclusion, respectively and similar to correlations observed in previous studies [8,27].

2.6.2. Secondary outcomes

Secondary outcomes were: 1) level of adherence (as a percentage) to wearing orthopedic shoes during one week at 3 and 6 months after inclusion; 2) change in adherence between 3 and 6 months after inclusion; 3) total wearing time during 1-year follow-up, 4) the proportion of participants (re-)experiencing ulceration up to 12 months after inclusion; 5) the participant experiences on the use and usability of their orthopedic shoes measured with the MOS at 6 and 12 months after inclusion; and 6) the participant-perceived HRQoL measured with the RAND-36 V2.0 at inclusion, 6 and 12 months after inclusion.

2.7. Sample size calculation

The original a-priori sample size calculation indicated that 220 participants would be needed for this study to provide 80 % power to detect the anticipated proportional difference of 20 % in adherent participants at 12 months in favor of the MI intervention group [18]. The target sample size could not be achieved, due to several logistic reasons and the outbreak of COVID-19 [18]. After incorporating some changes to the original study protocol, as described in our published protocol, and an extension of the planned inclusion period for 1 year, a total of 121 participants had been allocated. A post-hoc multilevel power analysis using the same assertions as the a priori sample size calculation indicated that the estimated power of the study to detect a 20 % difference between both groups was reduced to 59 %.

2.8. Statistical analysis

Statistical analysis was performed using SPSS statistical software version 28 (IBM, New York, USA). All tests of between- and within-group differences were two-sided and used a significance level of $p < 0.05$. Differences in the baseline characteristics between the intervention and control group were tested with t-tests, Mann-Whitney U tests, chi-square tests, or Fisher's exact tests, depending on the type and distribution of variables.

The primary outcome was analyzed both on an intention-to-treat (ITT) basis including all randomized participants and on an as-treated per-protocol (PP) basis including only those participants in the intervention group that had received the extra MI-consultation with an MI-trained podiatrist and those participants in the control group that did not receive an extra MI-consultation. A binary logistic mixed model with a random effect for podiatrist was originally planned for the primary outcome analysis [18]. However, such a model could not be adequately fitted because the clustering of participants per podiatrist was unbalanced, as several podiatrists had treated only one or two participants. Therefore, the between-group difference in the proportion of adherent participants at 3 and 6 months was tested using simple chi-square tests.

All secondary outcomes were analyzed on an ITT basis and missing data for secondary outcomes at the different time points were not imputed. Differences in the percentage of adherence, the differences in change in adherence, and the differences in total wearing time were tested using independent t-tests. Differences in the analyses for (re)ulceration were tested with t-tests or Mann-Whitney U tests for continuous, or chi-square tests for categorical variables. Between-group differences in the participant experiences on the use and usability of their orthopedic shoes as measured with the MOS at 6 and 12 months were tested with Mann-Whitney U tests for continuous or chi-square tests for categorical variables. Within-group changes between 6 and 12 months after inclusion in both groups were tested with Wilcoxon tests or Marginal Homogeneity tests. Finally, scores on participant-perceived health-related quality of life as measured with the RAND-36 V2.0 at inclusion, 6, and 12 months were analyzed using repeated measures linear mixed models with group, time, and group $\times$ time interaction as fixed factors. A compound symmetry covariance structure was used to model the repeated measurements for all eight domains.

3. Results

3.1. Baseline characteristics

The study flow diagram is shown in Fig. 1. Participants were

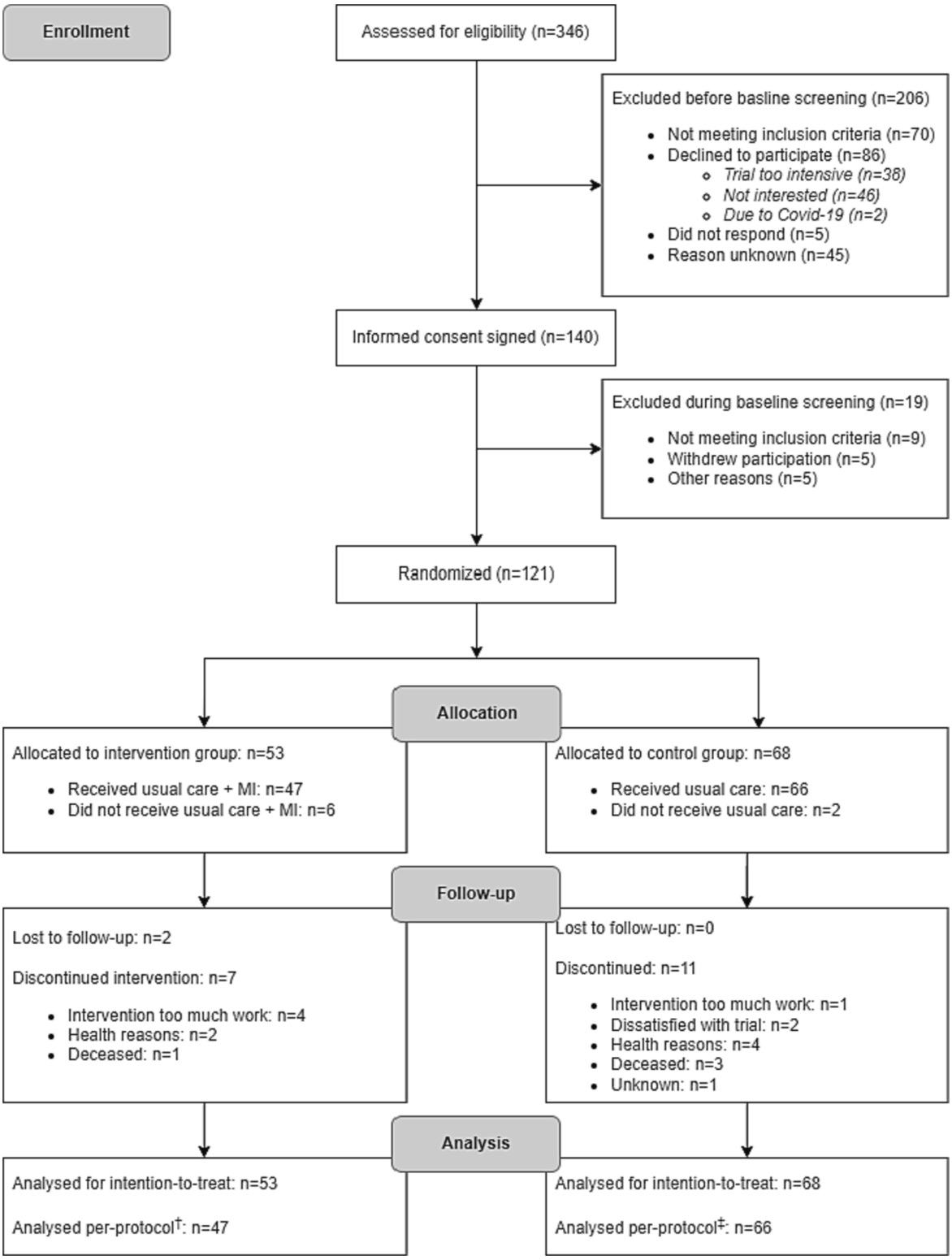

Fig. 1. Flow diagram for this study (CONSORT).

recruited between November 14, 2019, and April 7, 2021, and the last follow-up of the last participant ended on April 6, 2022. A total of 121 participants were included of whom 53 were allocated to the intervention group and 68 to the control group. In total, 34 podiatrists were involved in the study of which 18 were randomized to the intervention group. However, the number of participants was disproportionately distributed over the podiatrists; 49 % of the participants of the control group were treated by one podiatrist, while most MI-trained and untrained podiatrists had treated only one or two participants. Baseline participant characteristics are shown in Table 1. No significant baseline differences were observed between the two groups.

Table 1
Baseline characteristics of the intention-to-treat population.

Characteristic	All	Usual care + MI % (N)	Usual care % (N)	Missing values N (%)	p-values*
No. participants	121	44 % (53)	56 % (68)		
Age (years)	68.5 ± 8.3	68.8 ± 9.5	68.2 ± 7.2		0.743
Sex					0.888
Male	69 % (83)	68 % (36)	69 % (57)		
Female	31 % (38)	32 % (17)	31 % (21)		
Ethnic origin: Caucasian	99 % (120)	98 % (52)	100 % (68)		0.442
Living alone	33 % (40)	38 % (20)	29 % (20)	1 (1 %)	0.363
Education				1 (1 %)	0.150
Low	41 % (49)	34 % (18)	46 % (31)		
Medium	33 % (40)	30 % (16)	35 % (24)		
High	26 % (31)	34 % (18)	19 % (13)		
Employed	25 % (30)	25 % (13)	25 % (17)		0.952
Diabetes type					0.875
Type 1	10 % (12)	9 % (5)	10 % (7)		
Type 2	90 % (109)	91 % (49)	90 % (61)		
Diabetes duration (years)	17.8 ± 12.4	17.9 ± 13.8	17.7 ± 11.3	1 (%)	0.587
BMI (kg/m^2)	30.7 ± 5.2	30.7 ± 4.8	30.7 ± 5.6		0.738
Loss of protective sensation[†]	97 % (117)	98 % (52)	96 % (65)		NA[††]
Peripheral artery disease[‡]	23 % (28)	17 % (9)	28 % (19)		0.156
IWGDF Risk category[§]					NA[††]
Category 1	3 % (4)	2 % (1)	4 % (3)		
Category 2	36 % (44)	28 % (15)	43 % (29)		
Category 3	60 % (73)	70 % (37)	53 % (36)		
Foot deformity[¶]				4 (3 %)	NA[††]
Mild	7 % (9)	8 % (4)	7 % (5)		
Moderate	82 % (99)	83 % (44)	81 % (55)		
Severe	7 % (9)	4 % (2)	10 % (7)		
Amputation				1 (1 %)	NA[††]
No amputation	84 % (102)	83 % (44)	85 % (58)		
Lesser toe(s)	4 % (5)	8 % (4)	2 % (1)		
Hallux or ray	9 % (11)	8 % (4)	10 % (7)		
Forefoot	1 % (1)		2 % (1)		
Major	1 % (1)		2 % (1)		
Health related quality of life					
Physical functioning	54.0 ± 29.9	52.0 ± 30.1	55.6 ± 29.8	13 (11 %)	0.534
Social functioning	68.5 ± 26.2	65.6 ± 27.3	70.6 ± 25.4	13 (11 %)	0.353
Role functioning (physical)	47.8 ± 30.0	44.2 ± 30.1	50.5 ± 29.9	14 (12 %)	0.217
Role functioning (emotional)	76.2 ± 27.9	71.6 ± 30.1	79.6 ± 25.9	13 (11 %)	0.260
Mental health	73.6 ± 16.8	69.8 ± 18.8	76.5 ± 14.6	14 (12 %)	0.095
Vitality	55.3 ± 20.5	52.0 ± 20.1	57.8 ± 20.6	14 (12 %)	0.166
Pain	61.6 ± 25.4	59.1 ± 24.6	63.4 ± 26.0	12 (10 %)	0.305
General health	48.7 ± 19.7	45.3 ± 19.2	51.2 ± 19.8	16 (13 %)	0.139

Data are expressed as % (number) or mean ± SD. LOPS: loss of protective sensation, PAD: peripheral artery disease.

[†] Loss of protective sensation was confirmed present in both feet by the inability to sense the pressure of a 10-g Semmes-Weinstein monofilament at any of three plantar foot sites (hallux, first and third metatarsal head) or a vibration of 25 V at the hallux from a biothesiometer by the attending podiatrist.

[‡] Peripheral arterial disease was confirmed present when pedal pulses were nonpalpable and the ankle-brachial index was < 0.9 in the foot with the most recent episode of ulceration according to the PEDIS classification by the attending podiatrist [28].

[§] IWGDF Risk 1–3 [19] for eligible participants; IWFDF Risk category 1: moderate ulcer risk + LOPS + PAD; IWFDF Risk category 2: moderate ulcer risk + LOPS or PAD + foot deformity; IWFDF Risk category 3: high ulcer risk + LOPS or PAD, and one or more of the following: history of a foot ulcer, a lower-extremity amputation, end-stage renal disease.

[¶] The foot (left or right) with the most severe deformity determined classification per patient. Foot deformity was classified as "absent", "mild" (i.e. pes planus, pes cavus, hallux valgus or limitus, hammer toes, and lesser toe amputation), "moderate" (i.e. hallux rigidus, hallux or ray amputation, prominent metatarsal heads, claw toes), or "severe" (i.e. Charcot deformity, (fore)foot amputation and pes equines).

[††] A Chi-square test was not applicable because more than 25 % of the cells had an expected count of<5.

3.2. Primary outcome

A significantly higher proportion of participants in the control group (30.9 %) than in the intervention group (15.1 %) wore their orthopedic shoes ≥ 80 % of their steps taken 3 months after inclusion in the ITT analysis (Table 2). Although still numerically higher in the control group, the proportion of adherent participants was no longer significantly different between the intervention and control groups after 6 months (Table 2).

The PP analysis showed similar results. However, the difference in the proportions of adherent participants between the groups at 3 months did not reach statistical significance (Table 2).

3.3. Secondary outcomes

3.3.1. Level of adherence

The level of adherence to wearing orthopedic shoes was significantly higher in the control group on both the 3- and 6-month assessments (Table 3). The mean change in adherence between 3 and 6 months after inclusion was 1.4 percent point (*pp*) for the intervention group and 1.0 *pp* for the control group and did not change significantly in either the intervention group (p = 0.666) or control group (p = 0.666).

3.3.2. (Re)ulceration

During the 1-year follow-up in the entire study population, 37 unique participants developed 43 ulcers; 18 participants of the intervention

Table 2
Proportion of participants who sufficiently adhered[†] to wearing their orthopedic shoes.

	Intervention group *(N = 53)*	Control group *(N = 68)*	p-values
Adherence 3 months after inclusion (ITT)	15.1 %	30.9 %	0.044*
Adherence 6 months after inclusion (ITT)	13.2 %	22.1 %	0.210
Adherence 3 months after inclusion (PP)	17.0 %	31.8 %	0.076
Adherence 6 months after inclusion (PP)	14.9 %	21.2 %	0.395

[†] Adherent is defined as minimally 80 % of steps taken in their orthopedic shoes.

[*] Significantly different between groups, p < 0.05.

Table 3
Adherence in % of steps taken in orthopedic shoes (ITT).

	Intervention group		Control group		p-values
	Mean	**95 % CI**	**Mean**	**95 % CI**	
3 months after inclusion	50.9	43.8 to 57.9	60.9	55.0 to 66.8	0.029*
6 months after inclusion	49.5	42.2 to 56.9	59.9	54.3 to 65.6	0.025*

* Significantly different between groups, $p < 0.05$.

group developed 22 ulcers and 19 participants of the control group developed 21 ulcers. The proportion of participants who developed one or more ulcers during the 1-year follow-up was not significantly different between both groups (resp. 34 % and 28 %; $p = 0.476$). The mean (SD) number of ulcer-days in the intervention group was 52.7 (106.4) and 24.0 (59.7) days for the control group and did not significantly differ between the groups ($p = 0.312$). Mean (SD) time to first ulceration was 16.0 (18.6) versus 17.2 (17.2) weeks in the intervention versus control group, respectively ($p = 0.837$). In the total sample, mean adherence was not significantly different between those participants with at least one ulcer (60.1 %, SD = 26.0) versus those without an ulcer (54.9 %, SD = 25.0) 3 months after inclusion ($p = 0.297$). Six months after inclusion the results were similar (58.3 % (28.2) and 54.1 % (24.0) in those without an ulcer; $p = 0.434$).

3.3.3. *Use and usability of orthopedic shoes*

With respect to the self-reported use and usability of their orthopedic shoes, no clear differences were observed between the intervention and control groups at 6 and 12 months after inclusion (Table 4). The participants of the intervention group did experience the weight of their orthopedic shoes as heavier 6 months after inclusion compared to the participants of the control group ($p < 0.001$), but no longer at 12 months ($p = 0.759$).

In the intervention group, the participants experienced significantly less pain in their muscles due to their orthopedic shoes 12 months after inclusion compared to 6 months after inclusion ($p = 0.020$). In the control group, the participants experienced the weight of their orthopedic shoes as heavier at 12 months compared to 6 months after inclusion ($p = 0.022$). Besides, the participants of the control group were less satisfied with the communication by both the medical specialist and pedorthist/orthopedic shoe technician 12 months after inclusion compared with 6 months after inclusion (resp. $p = 0.003$, $p = 0.049$).

3.3.4. *Participant-perceived health-related quality of life (HRQoL)*

HRQoL scores were quite comparable between and stable within both groups at the different time points (Table 5). For all eight aspects of HRQoL, no significant effects were found for group, time, or the interaction between group and time. This indicates that mean HRQoL scores were not significantly different over time between the intervention and control group, did not significantly change over time in the entire study population, nor changed significantly differently over time between the two groups.

4. Discussion

People with diabetes at low-to-high risk of foot ulceration who received usual care plus MI focused on improving adherence to orthopedic shoes by a trained podiatrist were not significantly more or less adherent to wearing orthopedic shoes compared to participants who received usual care. Three months after inclusion, the proportion of adherent participants was even significantly higher in those that received usual care than in those who received usual care plus MI. This outcome suggests that the MI-intervention as implemented in its current form does not contribute to improving adherence to wearing orthopedic shoes in daily practice. Besides, no significant differences were found between the intervention and control group in the proportion of participants (re-)experiencing ulceration 12 months after inclusion, the participant experiences' on the use and usability of their orthopedic shoes, or the participant-perceived HRQoL.

Overall, the proportion of adherent participants in the current study was similar to those reported in previous studies [8,29–31]. In these

Table 4
Participant experiences on the use and usability of their orthopedic shoes.

	Intervention			Control			p-values between-group*	
	6 months	**12 months**	**p-value within-group***	**6 months**	**12 months**	**p-value within-group***	**6 months**	**12 months**
Effectiveness								
Change in pain (skin)† (n = 25, 23; 35, 34)‡	84 (57–97)	86 (75–96)	0.552	76 (63–96)	87 (69–94)	0.137	0.392	0.738
Change in pain (muscles)† (n = 27, 22; 35, 33)‡	79 (51–93)	87 (56–93)	0.020*	80 (64–95)	83 (61–95)	0.445	0.306	0.857
Change in sprains† (n = 23, 17; 21, 24)‡	97 (81–98)	92 (65–98)	0.656	92 (80–99)	89 (72–97)	0.432	0.733	0.916
Efficiency								
Donning/doffing OS†	75 (51–92)	75 (47–93)	0.768	75 (49–87)	70 (49–93)	0.542	0.802	0.666
Fit of OS†	89 (76–97)	90 (78–96)	0.962	90 (77–98)	85 (75–95)	0.120	0.075	0.433
Ease of walking with OS†	89 (71–69)	89 (70–96)	0.387	88 (72–97)	85 (71–96)	0.265	0.698	0.813
Weight of OS†	46 (26–52)	49 (31–53)	0.468	52 (46–60)	47 (25–55)	0.022*	<0.001*	0.759
Satisfaction								
Cosmetic appearance (patient)†	75 (56–94)	76 (50–93)	0.771	77 (51–91)	76 (66–93)	0.067	0.805	0.457
Cosmetic appearance (others)§			0.631			0.789	NA¶	NA¶
Very ugly or ugly	1 (2 %)	1 (2 %)		2 (3 %)	4 (6 %)			
Neutral	11 (21 %)	16 (30 %)		17 (25 %)	13 (19 %)			
Attractive or very attractive	25 (47 %)	18 (34 %)		29 (43 %)	29 (43 %)			
Do not know or missing	16 (30 %)	18 (34 %)		20 (29 %)	22 (32 %)			
Communication with MS†	90 (74–95)	85 (55–93)	0.393	90 (78–97)	84 (74–96)	0.003*	0.576	0.183
Communication with OST†	89 (81–96)	93 (78–95)	0.986	92 (79–97)	88 (75–97)	0.049*	0.847	0.495

Data are expressed as median (IQR), or n (%), or as indicated. MS = Medical Specialist; OS = orthopedic shoes; OST = orthopedic shoe technician.
* Significantly different, $p < 0.05$.
† Scores could range from 0 (lowest score possible) to 100 (highest score possible).
‡ Not all participants had wounds, pain or sprains, therefore the number of participants for these questions is indicated, for each group respectively.
§ Participants' answer on the question what others think about the cosmetic appearance of their OS.
¶ A Chi-square test was not applicable because more than 25 % of the cells had an expected count <5.

Table 5
Participant-perceived health-related quality of life.

Domain	Month	Intervention group		Control group		Fixed effects estimates (95 % CI)		
		Mean	**95 % CI**	**Mean**	**95 %CI**	**Group**	**Time**	**Group × Time**
Physical functioning	0	52.3	44.2–60.4	56.0	48.8–63.2	2.9 (−7.8 to 13.6)	−0.4 (−1.2 to 0.5)	0.2 (−0.3 to 0.7)
	6	51.4	43.3–59.6	53.6	46.4–60.9			
	12	50.1	41.8–58.3	56.3	48.9–63.7			
Social functioning	0	65.6	58.1–73.2	70.2	63.6–76.7	1.6 (−8.2 to 11.3)	−0.1 (−1.5 to 1.3)	0.0 (−0.8 to 0.8)
	6	72.4	64.8–80.1	68.0	61.2–74.7			
	12	64.0	56.0–72.0	69.0	62.0–76.1			
Role functioning (physical)	0	44.5	36.1–52.8	50.9	43.5–58.3	6.0 (−4.9 to16.9)	−0.3 (−1.6 to 1.1)	0.1 (−0.7 to 0.9)
	6	44.6	36.1–53.1	50.3	42.7–57.9			
	12	42.2	33.5–51.0	49.7	41.8–57.5			
Role functioning (emotional)	0	70.8	62.4–79.2	78.9	71.5–86.2	8.9 (−1.9 to 19.6)	−0.4 (−1.9 to 1.1)	−0.2 (−1.1 to 0.7)
	6	63.6	55.1–72.0	72.8	65.0–80.5			
	12	63.6	54.8–72.4	69.5	61.6–77.3			
Mental health	0	69.9	65.0–74.8	76.1	71.8–80.4	5.4 (−1.0 to 11.8)	0.5 (−0.3 to 1.2)	−0.3 (−0.7 to 0.2)
	6	74.2	69.5–79.4	76.7	72.3–81.2			
	12	72.2	67.1–77.4	75.3	70.8–79.9			
Vitality	0	51.9	46.0–57.8	57.2	51.9–62.4	5.2 (−2.4 to 13.0)	−0.1 (−1.0 to 0.8)	0.1 (−0.5 to 0.6)
	6	52.3	46.3–58.3	58.3	52.9–63.7			
	12	51.7	45.5–57.9	58.1	52.5–63.6			
Pain	0	59.0	51.7–66.4	63.5	57.1–69.9	3.5 (−6.0 to 13.0)	0.4 (−0.8 to 1.6)	−0.2 (−0.9 to 0.5)
	6	60.3	52.8–67.7	60.4	53.8–67.0			
	12	61.5	53.8–69.1	63.8	57.0–70.6			
General health	0	45.5	39.7–51.3	50.7	45.5–55.8	4.5 (−3.1 to 12.1)	0.3 (−0.5 to 1.1)	−0.1 (−0.6 to 0.4)
	6	46.8	40.9–52.6	49.5	44.0–54.8			
	12	48.1	42.1–54.0	52.6	47.2–58.0			

studies, 22–36 % of people with diabetes at risk for ulceration wore their orthopedic shoes all day or at least greater than 80 % of daytime. However, with respect to the level of adherence, Waaijman et al. showed that people with diabetes at high risk for ulcer recurrence wore their orthopedic shoes on average in 71 % of the steps taken [8]. In the current study, the mean level of adherence was 61 % in the control group and 51 % in the intervention group 3 months after inclusion and this level was stable 6 months after inclusion. One possible explanation for this lower level of adherence is that all participants in the study of Waaijman and colleagues were at high risk of foot re-ulceration, because of their recently healed plantar ulcer, making the importance of wearing orthopedic shoes much higher compared to our population that also included people at low or moderate risk of ulceration [8].

Secondly, the current study mostly took place during the COVID-pandemic. Due to the pandemic, many people were forced to work more from home and likely stayed more at home indoors in general. In their study, Waaijman et al. [8] showed that adherence to orthopedic shoes was much lower indoors than outdoors. This may partly explain the lower level of adherence in the current study, as only a few participants owned custom-made indoor shoes, which may have limited the use of orthopedic shoes indoors. Keukenkamp et al. recently showed that custom-made indoor shoes increased adherence to wearing orthopedic shoes in both the short-term and long-term in people at risk of diabetic foot ulceration [32]. In the current study we did not assess whether participants were indoors or outdoors when wearing their shoes, something that we do recommend registering in future research. Finally, the satisfaction of the participants with the communication with their podiatrist was not measured. It is possible that the application of MI by the podiatrist had a negative effect on the adherence to wearing orthopedic shoes, because most participants have been seeing a podiatrist already for years and are likely to be unfamiliar with this way of communicating with their podiatrist [17]. Perhaps not only the podiatrist has to get used to applying MI, but the participant may also have to get used to the podiatrist using MI. By encouraging MI to be included already in primary podiatrist training, it is likely that future patients already become accustomed to this way of communicating early on in their treatment.

The lower adherence in the intervention group compared to the usual care group was surprising and the reason for this remains unclear, also because no significant differences were found between the baseline characteristics of both groups. This difference in adherence may be caused by some limitations of the study. First of all, it is unknown whether the intervention and control group differed from each other at inclusion regarding adherence to wearing orthopedic shoes, as no baseline adherence measurement was performed. No baseline adherence measurement was done, because clinical practice experience showed that only 3 months after receiving the orthopedic shoes the majority of the patient could wear the shoes all day long, because they had to get used to the shoes and adjustments had to be made. However, for future research we recommend to do a baseline measurement if possible Secondly, the results of this study may be limited by the implementation of the MI-intervention in its current dose and form. In this study, the participants had only one MI-consultation with an MI-trained podiatrist, who applied MI in daily clinical practice at a solid beginner level. Previous research showed that the number of brief MI-consultations was unrelated to the outcome, which suggests that longer time in a single MI-visit combined with booster-sessions may promote better outcomes [33]. This is in line with Keukenkamp et al, who suggested based on their study that booster MI-sessions may improve the outcome [4]. Besides, Keeley and colleagues showed that to realize the full benefits of MI healthcare providers may need to invest slightly more time in each visit [34]. In their systematic review and meta-analysis Lundahl et al. showed that just a small amount of extra time with a patient per consultation to build a relationship and evoke change talk resulted in a 10–15 % improvement [35]. Therefore, more research is needed on the application and required dose of MI to better inform clinical practice how to improve adherence to wearing orthopedic shoes. Thirdly, as the purpose of the current study was to evaluate the effectiveness of one MI-consultation in daily practice settings, the importance of highly external valid outcomes overrode aspects of internal validity, such as equal and normal distribution of the participants over the podiatrists. As a result, the number of participants was disproportionately distributed over the podiatrists, with almost half of the participants of the control group being treated by one and the same podiatrist. Therefore, it is possible that the characteristics and the patient-healthcare provider relationship of this specific podiatrist disproportionately influenced the level of adherence of the control group and possibly thereby also the results of the comparison with the intervention group on the level of

adherence. As multilevel analyses were not possible to take these differences between podiatrists into account, this may have led to confounding. In addition, the current study concerns research in daily clinical practice where the aim was to investigate something that could also be implemented in that clinical practice. Multiple MI-consultations are much more difficult to implement in practice and would not have been necessary if the current study showed that one MI-consultation was effective. Follow-up research, such as qualitative interviews with the podiatrists and/or participants, could shed more light on the reasons for both the overall low adherence rate and the even lower adherence in MI intervention group.

Regarding the perceived use and usability of orthopedic shoes, the results of the current study did show that the participants of the intervention group experienced the weight of their orthopedic shoes as significantly heavier than the participants of the control group 6 months after inclusion. This result is in line with previous research, in which Van Netten et al. found a significant difference regarding the weight of orthopedic shoes between frequent and occasionally users [11]. However, it is unlikely that this difference 6 months after inclusion alone would explain the difference in the level of adherence between the two groups in the current study. Besides, Arts et al. showed that comfort (ease of walking with OS in the current study) and the appearance/style of the shoe were perceived as the most important aspects for wearing orthopedic shoes [36], while Van Netten et al. found the communication with the medical specialist and pedorthist to be essential to influence a patient's decision to use orthopedic shoes [10,11]. Even though the participants in the current study were satisfied with the communication with the medical specialist and pedorthist, adherence to wearing orthopedic shoes was low.

In comparison to previous studies, the HRQoL scores of the participants in the current study were clearly worse than those of the general Dutch population [37] and people with diabetes [38]. However the scores were similar to people with diabetes and high risk of ulceration [39,40], and better than in people with a current ulcer [40–42]. Therefore, the HRQoL of participants included in the current study appears to be representative of the population of people with diabetes at risk of ulceration.

In conclusion, the current implementation of MI by an MI-trained podiatrist in addition to usual care did not improve adherence to wearing orthopedic shoes 3 and 6 months after inclusion nor 1-year outcomes in ulcer prevention. The relation between effectiveness of MI and adherence to wearing orthopedic shoes may be more complex than expected. It may also be affected by other variables as shown in previous studies and limited due to implementation complexities in clinical practice settings, such as the reimbursement of an appointment with the podiatrists by the health insurance. Therefore, although MI may have the potential to increase adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration, it does not seem a simple standalone solution. A higher dose of MI or podiatrists applying MI at a higher level may be required to substantially improve the level of adherence to wearing orthopedic shoes and should be investigated in future trials.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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References

[1] Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med 2017;376(24):2367–75.
[2] Zhang P, et al. Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis (dagger). Ann Med 2017;49(2):106–16.
[3] van Acker K, et al. Burden of diabetic foot disorders, guidelines for management and disparities in implementation in Europe: a systematic literature review. Diabetes Metab Res Rev 2014;30(8):635–45.
[4] Keukenkamp R, et al. An Explorative Study on the Efficacy and Feasibility of the Use of Motivational Interviewing to Improve Footwear Adherence in Persons with Diabetes at High Risk for Foot Ulceration. J Am Podiatr Med Assoc 2018;108(2):90–9.
[5] Bus SA, et al. Effect of custom-made footwear on foot ulcer recurrence in diabetes: a multicenter randomized controlled trial. Diabetes Care 2013;36(12):4109–16.
[6] van Netten JJ, et al. Prevention of foot ulcers in the at-risk patient with diabetes: a systematic review. Diabetes Metab Res Rev 2020;36(Suppl 1):e3270.
[7] Bus SA, van Netten JJ. A shift in priority in diabetic foot care and research: 75% of foot ulcers are preventable. Diabetes Metab Res Rev 2016;32(Suppl 1):195–200.
[8] Waaijman R, et al. Adherence to wearing prescription custom-made footwear in patients with diabetes at high risk for plantar foot ulceration. Diabetes Care 2013;36(6):1613–8.
[9] Bus SA, et al. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update). Diabetes Metab Res Rev 2020;36(Suppl 1):e3269.
[10] van Netten JJ, et al. What influences a patient's decision to use custom-made orthopaedic shoes? BMC Musculoskelet Disord 2012;13:92.
[11] van Netten JJ, et al. Long-term use of custom-made orthopedic shoes 1 5-year follow-up study. J Rehabil Res Dev 2010;47(7):643–9.
[12] van Netten JJ, et al. Communication techniques for improved acceptance and adherence with therapeutic footwear. Prosthet Orthot Int 2017;41(2):201–4.
[13] Miller WR, Rollnick S. *Motivational interviewing: Helping people change, 3rd edition*. Motivational interviewing: Helping people change, 3rd edition. 2013, New York, NY, US: Guilford Press. 29.
[14] Miller WR, Rollnick S. *Motivational interviewing: Helping people change, 3rd edition*. Motivational interviewing: Helping people change, 3rd edition. 2013, New York, NY, US: Guilford Press. 482.
[15] Gabbay RA, et al. Motivational interviewing by podiatric physicians: a method for improving patient self-care of the diabetic foot. J Am Podiatr Med Assoc 2011;101(1):78–84.
[16] Kaczmarek T, et al. Effects of training podiatrists to use imagery-based motivational interviewing when treating people with diabetes-related foot disease: a mixed-methods pilot study. J Foot Ankle Res 2021;14(1):12.
[17] Jongebloed-Westra M, et al. Attitudes and experiences towards the application of motivational interviewing by podiatrists working with people with diabetes at high-risk of developing foot ulcers: a mixed-methods study. J Foot Ankle Res 2022;15(1):62.
[18] Jongebloed-Westra M, et al. Using motivational interviewing combined with digital shoe-fitting to improve adherence to wearing orthopedic shoes in people with diabetes at risk of foot ulceration: study protocol for a cluster-randomized controlled trial. Trials 2021;22(1):750.
[19] Schaper NC, et al. Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). Diabetes Metab Res Rev 2020;36(Suppl 1):e3266.
[20] Lutjeboer T, et al. Validity and feasibility of a temperature sensor for measuring use and non-use of orthopaedic footwear. J Rehabil Med 2018;50(10):920–6.
[21] Kooiman TJ, et al. Reliability and validity of ten consumer activity trackers. BMC Sports Sci Med Rehabil 2015;7:24.
[22] van Netten JJ, et al. Development and reproducibility of a short questionnaire to measure use and usability of custom-made orthopaedic shoes. J Rehabil Med 2009;41(11):913–8.
[23] Vander Zee KI, et al. Psychometric qualities of the rand 36-item health survey 1.0: A multidimensional measure of general health status. Int J Behav Med 1996;3(2):104.
[24] van der Zee KI, Sanderman R, *Het meten van de algemene gezondheidstoestand met de Rand-36. Een handleiding*. Research Institute SHARE 2012.
[25] Bus SA, Waaijman R, Nollet F. New monitoring technology to objectively assess adherence to prescribed footwear and assistive devices during ambulatory activity. Arch Phys Med Rehabil 2012;93(11):2075–9.
[26] Lutjeboer T, et al. *Groningen algorithm, version 2. Github*. [cited 2022 December 1]; Available from: https://github.com/CHulshof/Orthotimer_algorithm.
[27] Jarl G, et al., Adherence and Wearing Time of Prescribed Footwear among People at Risk of Diabetes-Related Foot Ulcers: Which Measure to Use? 2023. **23**(3): p. 1648.

[28] Schaper NC. Diabetic foot ulcer classification system for research purposes: a progress report on criteria for including patients in research studies. Diabetes Metab Res Rev 2004;20(Suppl 1):S90–5.
[29] Macfarlane DJ, Jensen JL. Factors in diabetic footwear compliance. J Am Podiatr Med Assoc 2003;93(6):485–91.
[30] Knowles EA, Boulton AJM. Do people with diabetes wear their prescribed footwear? Diabet Med 1996;13(12):1064–8.
[31] McCabe CJ, Stevenson RC, Dolan AM. Evaluation of a diabetic foot screening and protection programme. Diabet Med 1998;15(1):80–4.
[32] Keukenkamp R, et al. Custom-made footwear designed for indoor use increases short-term and long-term adherence in people with diabetes at high ulcer risk. BMJ Open Diabetes Res Care 2022;10(1).
[33] Otto C, et al. Brief intervention in general hospital for problematic prescription drug use: 12-Month outcome. Drug Alcohol Depend 2009;105(3):221–6.
[34] Keeley RD, et al. Motivational interviewing improves depression outcome in primary care: A cluster randomized trial. J Consult Clin Psychol 2016;84(11):993–1007.
[35] Lundahl B, et al. Motivational interviewing in medical care settings: a systematic review and meta-analysis of randomized controlled trials. Patient Educ Couns 2013;93(2):157–68.
[36] Arts ML, et al. Perceived usability and use of custom-made footwear in diabetic patients at high risk for foot ulceration. J Rehabil Med 2014;46(4):357–62.
[37] Picavet HS, Hoeymans N. Health related quality of life in multiple musculoskeletal diseases: SF-36 and EQ-5D in the DMC3 study. Ann Rheum Dis 2004;63(6):723–9.
[38] Kleefstra N, et al. Cross-sectional relationship between glycaemic control, hyperglycaemic symptoms and quality of life in type 2 diabetes (ZODIAC-2). Neth J Med 2005;63(6):215–21.
[39] Perrin BM, et al. Health-related quality of life and associated factors in people with diabetes at high risk of foot ulceration. J Foot Ankle Res 2022;15(1):83.
[40] Nabuurs-Franssen MH, et al. Health-related quality of life of diabetic foot ulcer patients and their caregivers. Diabetologia 2005;48(9):1906–10.
[41] Yekta Z, Pourali R, Ghasemi-Rad M. Comparison of demographic and clinical characteristics influencing health-related quality of life in patients with diabetic foot ulcers and those without foot ulcers. Diabetes Metab Syndr Obes 2011;4:393–9.
[42] Khunkaew S, Fernandez R, Sim J. Health-related quality of life among adults living with diabetic foot ulcers: a meta-analysis. Qual Life Res 2019;28(6):1413–27.