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

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Background: In this explorative study, we assessed the effect and feasibility of using motivational interviewing to improve footwear adherence in persons with diabetes who are at high risk for foot ulceration and show low adherence to wearing prescribed custom-made footwear.

Methods: Thirteen individuals with diabetes, ulcer history, and low footwear adherence (ie, <80% of steps taken in prescription footwear) were randomly assigned to standard education (ie, verbal and written instructions) or to standard education plus two 45-min sessions of motivational interviewing. Adherence was objectively measured over 7 days using ankle- and shoe-worn sensors and was calculated as the percentage of total steps that prescribed footwear was worn. Adherence was assessed at home and away from home at baseline and 1 week and 3 months after the intervention. Feasibility was assessed for interviewer proficiency to apply motivational interviewing and for protocol executability.

Results: Median (range) baseline, 1-week, and 3-month adherence at home was 49% (6%–63%), 84% (5%–98%), and 40% (4%–80%), respectively, in the motivational interviewing group and 35% (13%–64%), 33% (15%–55%), and 31% (3%–66%), respectively, in the standard education group. Baseline, 1-week, and 3-month adherence away from home was 91% (79%–100%), 97% (62%–99%) and 92% (86%–98%), respectively, in the motivational interviewing group and 78% (32%–97%), 91% (28%–98%), and 93% (57%–100%), respectively, in the standard education group. None of the differences were statistically significant. Interviewer proficiency was good, and the protocol could be successfully executed in the given time frame.

Conclusions: Footwear adherence at home increases 1 week after motivational interviewing to clinically relevant but not statistically significant levels (ie, 80%) but then returns over time to baseline levels. Away from home, adherence is already sufficient at baseline and remains so over time. The use of motivational interviewing seems feasible for the given purpose and patient group. These findings provide input to larger trials and provisionally suggest that additional or adjunctive therapy may be needed to better preserve adherence. (J Am Podiatr Med Assoc 108(2): 90-99, 2018)

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Foot ulceration is one of the major health problems for people with diabetes mellitus. It is estimated to affect 19% to 34% of people with diabetes at some time in their lives.[1] Foot ulceration is an important precursor to foot infection and amputation. Furthermore, it negatively affects quality of life[2] and leads to a substantial economic burden.[3] Therefore,

prevention of ulceration is of paramount importance.

Preventive treatment often involves the use of prescription custom-made footwear, aiming to reduce ulcer risk by redistributing and reducing foot pressures and providing proper fit.[4,5] Our research group found that pressure-improving custom-made footwear is effective in preventing foot ulcer recurrence, if it is worn as recommended.[6] However, in this study, half of the patients were shown to have low adherence, ie, less than 80% of the steps taken per day were in prescribed footwear. Moreover, footwear adherence at home was much lower than away from home, although patients walked significantly more at home.[7] These results confirm previously reported findings on footwear adherence in this patient population[8,9] and demonstrate that nonadherence is a problem in high-risk persons with diabetes and should, therefore, be improved.

Apart from good footwear, patient education is a cornerstone of preventive treatment[10] and is generally aimed at increasing knowledge and improving self-care behavior and adherence to treatment. However, the evidence base to support patient education to prevent foot ulceration in persons with diabetes is small.[10] The common method used and studied in patient education is the provision of information. However, to change one's behavior may require additional intervention. Brief interventions using motivational interviewing are shown to be evidence-based methods in several domains, mainly in substance use disorders, but also in health behaviors related to diet, exercise programs, and treatment adherence.[11,12] Although not all studies report positive outcomes, several reviews suggest that motivational interviewing is effective in diabetes care.[13-15] Motivational interviewing is a person-centered, directive method for enhancing motivation for change by exploring and resolving ambivalence to change.[16] Such ambivalence to change in behavior may also exist in persons with diabetes who are nonadherent to wearing prescribed protective footwear.

The effect of motivational interviewing on footwear adherence has not yet been investigated in persons with diabetes who are at high foot ulcer risk. Given the suggested conceptual behavioral similarity with nonadherence in general diabetes care, we hypothesize that motivational interviewing has a positive effect on footwear adherence. Because of the complete lack of existing knowledge on efficacy and feasibility, we aimed to explore the effect of motivational interviewing on footwear adherence and to assess the feasibility of applying motivational interviewing in persons with diabetes who are at high risk for foot ulceration and who have low adherence to wearing prescribed custom-made footwear.

Patients and Methods

Patients

Patients were recruited from the outpatient diabetic foot clinic of the Academic Medical Center in Amsterdam, the Netherlands. The inclusion criteria were age 18 years or older, diabetes mellitus type 1 or 2, history of foot ulceration, and the possession of prescription footwear dispensed at least 3 months before inclusion. The exclusion criteria were current foot ulcer, inability to walk, participation in another study that may influence the study outcomes, and inability to read and understand the study instructions. From each patient, written informed consent was obtained before inclusion. The Medical Ethical Committee of the Academic Medical Center approved the study.

Randomization and Blinding

This study was designed as an explorative trial in which participants were randomly allocated to one of two study arms in a balanced manner. First, a 7-day baseline measurement of footwear adherence was conducted in each patient. Those who wore their prescribed footwear for less than 80% of the steps taken either inside or outside their homes were classified as having low adherence. These patients were randomly assigned to either standard education (control group) or standard education plus two sessions of motivational interviewing (intervention group). To ensure a balanced treatment allocation, block randomization with variable block sizes was used. A sealed envelope randomization sequence was created and managed by an independent investigator. Participants were not blinded to treatment allocation, but we blinded them at baseline to the goal of monitoring treatment adherence. The participants' rehabilitation medicine specialist was blinded to treatment allocation. Patients were asked not to disclose their study allocation to their rehabilitation medicine specialist.

Interventions

Each patient in the study received standard education, which consisted of written and verbal infor-

mation given by the rehabilitation medicine specialist at footwear delivery on the proper use of footwear and the importance of wearing this footwear to prevent complications. Written information included a brochure providing shoe-wearing advice.

Motivational interviewing was given in addition to standard education in the intervention group and consisted of two 45-min sessions, 1 week apart. It focused mainly on enhancing the patient's knowledge and motivation for change. The sessions followed a protocol developed by the investigators. During the first session of motivational interviewing, first the patients' footwear adherence over 1 week measured at baseline was presented and discussed. These data were presented in a histogram containing the day-by-day total footwear adherence, the adherence for being at home and away from home, and the average daily step count. An example histogram can be found elsewhere.[17] Second, the reasons for low adherence were discussed with the patient, as well as the reasons why the patient would wear the footwear. Subsequently, the patient was presented with outcomes of studies showing evidence-based data on the importance of wearing prescription footwear, specifically, the results of two randomized controlled trials on the topic.[6,18] The second session focused on the change in behavior and goal setting. First, the patient was asked about the advantages and disadvantages of wearing and not wearing the prescribed shoes, and answers were recorded in a table format and then discussed. Second, the readiness to change footwear-wearing behavior was examined by asking the patient how relevant a change in behavior would be and, subsequently, how confident the patient was that he or she could achieve and maintain a change in behavior. Relevance and confidence were assessed using a 10-point scale. This part concluded with asking the following question: "Do you want to change your footwear-wearing behavior?" If the answer was "yes," an intention-to-change plan was made. This plan contained the following items: goal setting in changing footwear use, with options ranging from "not willing to change" to "change instantly"; determining a percentage of footwear use that the patient wants to achieve; and discussing the measures of self-control to achieve this goal, which could include avoiding activities, persons, or places that may evoke nonadherence; initiating behavioral alternatives; and defining rewards and alternative rewards when short-term goals are achieved.

In both sessions, principles and techniques of motivational interviewing were applied to evoke change talk: 1) basic skills such as the ability to ask open-ended questions, provide affirmations and summaries, and engage in reflective listening; 2) strategies to elicit change talk, such as asking evocative questions, query extremes, looking back and forward, and using change rulers; and 3) principles of motivational interviewing, such as expressing empathy, developing discrepancy, rolling with resistance, and supporting self-efficacy and autonomy.[16]

The two investigators (R.K. and S.A.B.) conducting the motivational interviewing with the participants underwent a training program consisting of 1) a 16-hour group training in motivational interviewing; 2) three 2-hour private training sessions aimed at managing the specific motivational interviewing study protocol; 3) two simulation sessions with persons with diabetes with direct verbal feedback from the trainer; and 4) written and verbal feedback from the trainer after the first two motivational interviewing sessions in the study. This feedback was based on recorded and systematically coded interviews using the Coding System for Integrity of Treatment–Motivational Interviewing (CoSIT-MI). The CoSIT-MI is a Dutch validated instrument that measures therapists' proficiency in conducting motivational interviewing; it includes all of the items on the Motivational Interviewing Treatment Integrity code.[19] A health psychologist (M.J.M.) educated in training motivational interviewing by the Motivational Interviewing Network of Trainers was responsible for the training.

Assessments

Footwear adherence was assessed at baseline and 1 week and 3 months after the intervention. In addition, at baseline, demographic and disease characteristics of each patient were collected.

Footwear adherence was determined through a continuous 7-day objective assessment of footwear use and daily step activity. Footwear use was assessed using the @monitor (Department of Medical Technology and Innovation, Academic Medical Center, Amsterdam, the Netherlands), a small, temperature-based sensor placed inside the prescribed shoes.[7,17] Footwear use was assessed at 1-minute intervals according to previously described methods.[17] A maximum of 2 pairs of prescribed shoes were fitted with the @monitor. If patients had more pairs of prescription footwear,

they were instructed not to wear these other pairs during the 7-day measurement.

Daily step activity was measured simultaneously and synchronously with footwear use using a step activity monitor strapped around the ankle (StepWatch; Orthocare Innovations LLC, Edmonds, Washington). The StepWatch records number of steps at 1-min intervals. Patients were instructed to wear the StepWatch at all times, which included sleeping, showering, and bathing. In previous studies, the @monitor and StepWatch activity monitor proved to be valid and reliable.[17,20]

Patients were asked to complete a daily log during the 7-day assessment for the periods that they were cycling, away from home, or not wearing the step activity monitor. Monitors and logs were returned through postal mail after the 7-day assessment.

The feasibility of applying motivational interviewing was assessed by evaluating 1) the proficiency of the investigators who conducted the interviews using the CoSIT-MI (assessed by the trainer) and 2) the recorded motivational interviewing sessions for aspects such as duration of the sessions, success in executing and completing the protocol, and ability of the patient to comprehend the protocol components (as judged by the investigator).

Data Analysis

Footwear adherence and daily step count were calculated from raw data from the monitors using custom-built software in Matlab R2014 (The MathWorks Inc, Natick, Massachusetts). A minimum of four complete days of recording, including one weekend day, was required for inclusion in the analysis. Periods of cycling were subtracted from the step activity data. When both the @monitor and the step activity monitor showed activity during recording, it was assumed that the patient walked with the prescribed shoes. If only step activity was recorded, we assumed barefoot walking or walking in nonprescribed shoes.

Adherence was defined as the percentage of total steps during the full recording period that the prescribed footwear was worn and was calculated as:

$$Adherence = \frac{\sum \ steps\ wearing\ prescribed\ footwear}{\sum \ steps}$$

To differentiate between adherence at home and away from home, the reported time moments in the daily log that the patient was away from home were used.

Statistical Analysis

Descriptive statistics were used for patient characteristics, adherence, and step count. Differences in patient characteristics were assessed with the Mann-Whitney U test and the Fisher exact test. The Friedman test was used to assess differences in adherence and step count within groups, and the Mann-Whitney U test for between-group differences. For all of the tests, a significance level of $P < .05$ was used. Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp, Armonk, New York). Individual results of patients randomized to the motivational interviewing group are described as case reports.

Results

A flow diagram for patient inclusion and analysis is shown in Fig. 1. Thirteen patients were randomized to either the intervention (n = 6) or control (n = 7) group. One patient in the motivational interviewing group dropped out because of withdrawing participation. Two patients in the standard education group dropped out because of a fractured foot (n = 1) and death (n = 1). These events were not related to the study intervention. Baseline characteristics of the ten analyzed patients are presented in Table 1.

Adherence

Results for footwear adherence are shown in Table 2. Median footwear adherence in the motivational interviewing group was 67% at baseline, 90% at 1 week, and 56% at 3 months after the intervention. In the standard education group, median adherence was 45% at baseline, 47% at 1 week, and 59% at 3 months. Median adherence at home was 49% at baseline, 84% at 1 week, and 40% at 3 months in the motivational interviewing group and 35%, 33%, and 31%, respectively, in the standard education group. Adherence away from home was 91% at baseline, 97% at 1 week, and 92% at 3 months in the motivational interviewing group and 78%, 91%, and 93%, respectively, in the standard education group. None of the changes within and between the groups were statistically significant.

Daily Step Count

Results for daily step count are shown in Table 3. In the motivational interviewing group, the median daily step count at home was 8,200 at baseline, 6,973

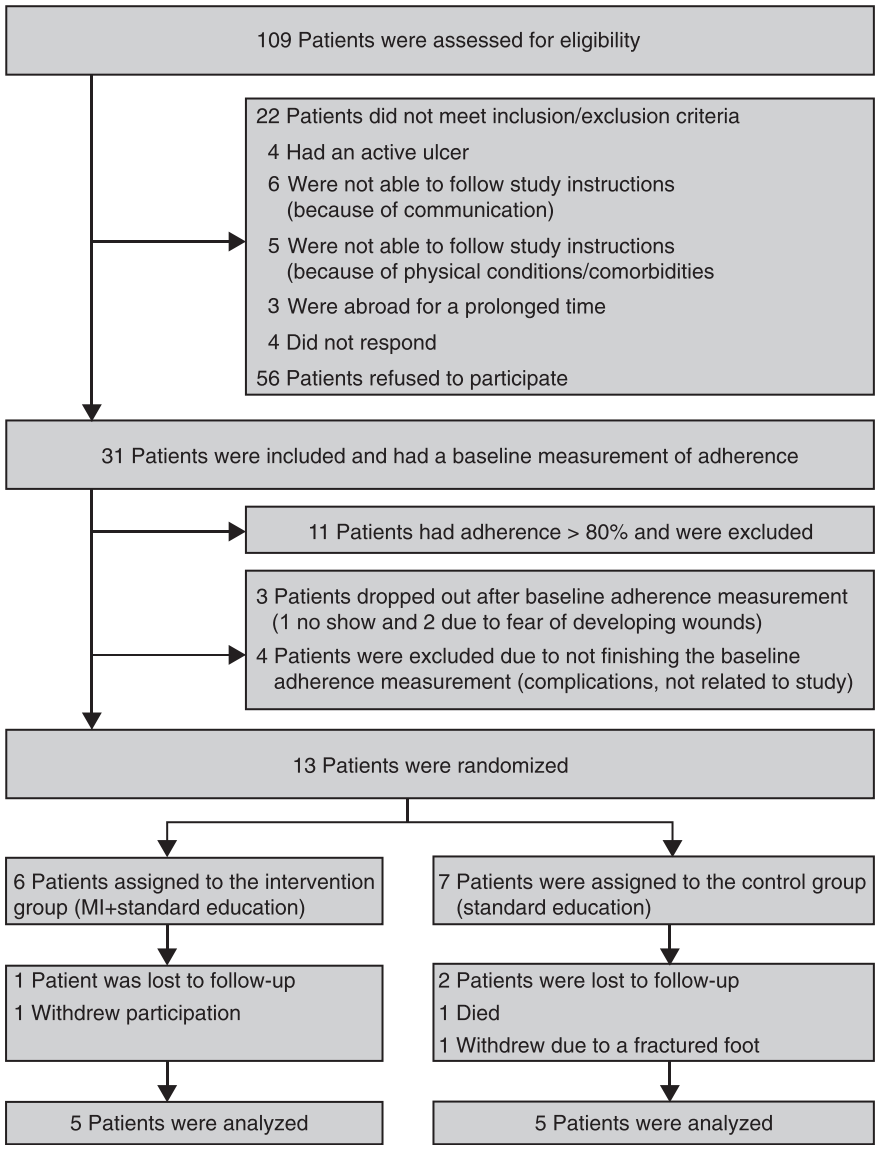

Figure 1. Study flow diagram. MI, motivational interviewing.

at 1 week, and 5,367 at 3 months after the intervention. Away from home, this was 2,587, 2,536, and 3,122, respectively. In the standard education group, the median daily step count at home was 3,897 at baseline, 3,919 at 1 week, and 4,229 at 3 months. Away from home, this was 2,931, 4,244, and 3,228, respectively. None of the changes within and between the groups were statistically significant.

Case Reports

The individual results on overall adherence for participants in the motivational interviewing group are shown in Fig. 2.

Case 1 was a man of Surinamese origin, aged 51 years and employed, who had type 2 diabetes for more than 25 years. This patient recalled having his last ulcer years ago; exact data were missing. His overall adherence at baseline was 67%. Adherence at home was 63%, away from home 100%. After the intervention, adherence at home increased to 95% at 1 week and decreased to 57% at 3 months. Adherence away from home decreased slightly to 96% at 1 week and 89% at 3 months. During the motivational interviewing session, he was able to explain why it was important to wear the prescribed footwear. Reasons for not wearing the shoes inside the house were that donning and doffing of his shoes was more difficult than with his slippers, he

Table 1. Baseline Characteristics of the Ten Protocol Completers

Characteristic	Motivational Interviewing Group (n = 5)	Standard Education Group (n = 5)
Age (median [range] [years])	57 (51–73)	62 (45–65)
Sex, M/F (No.)	5/0	4/1
BMI (median [range])	24.2 (22.6–32.6)	27.8 (21.2–37.8)
Diabetes, type 1/2 (No.)	1/4	1/4
Diabetes duration (median [range] [years])	29 (15–47)	17 (14–49)
HbA_{1c} (median [range] [mmol/mol])	55 (38–82)	62 (52–98)
Loss of protective sensation (No.)	5	5

Note: No significant differences between groups were found. Of the 13 patients randomized, three were excluded from analysis: one in the motivational interviewing group because of withdrawing participation and two in the standard education group because of a fractured foot and death (not related to the study intervention).

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HbA_{1c}, hemoglobin A_{1c}.

spent a lot of time on the couch, and he thought that he hardly took steps inside his home (although his data showed 4,886 steps per day in the house, which was 89% of his total number of daily steps). He mentioned that he never saw the benefit of wearing his prescription shoes indoors, but after discussing the importance of wearing shoes based on scientific results, he clearly understood and even reiterated the benefits and importance and was prepared to wear his prescription shoes more at home. In his intention-to-change plan he stated that he would wear his shoes at home, every day, all of the time, starting right away.

Case 2 was a white man aged 64 years, retired, with type 1 diabetes for more than 40 years. Previous foot ulcers occurred in 1983 and 2011. His overall footwear adherence at baseline was 68%; at home this was 62%, away from home 87%. One week after the intervention, adherence increased to 90%, which was retained after 3 months at 90%. Adherence at home increased to 84% at 1 week and was 80% at 3 months. During the motivational interviewing sessions, it seemed that the patient was not aware of the high number of steps he took daily inside his home (8,200 steps, 76% of his total number of daily steps). He did not have a clear reason for not wearing his prescribed shoes at home, other than that it was out of habit. The patient expressed his satisfaction with the prescribed shoes several times. He did not have any problem with shoe comfort or appearance. After providing the information on scientific results, he realized the importance of the protective properties of his prescribed shoes and was able to name several (future) benefits of wearing the shoes (ie, staying active and independent). In his intention-to-change plan, he planned to increase adherence at home from 62% to 75%, on a gradual basis. His confidence in wearing his shoes more often was rated as a 9 on a 10-point scale.

Case 3 was a 57-year-old white man who was employed during inclusion in the study but was forced to stop working for health reasons after the baseline measurement. He was diagnosed as having

Table 2. Footwear Adherence Overall, at Home, and Away from Home at Baseline and 1 Week and 3 Months After the Intervention

Footwear Adherence	Motivational Interviewing Group	Standard Education Group	*P* Value
Overall (%)			
Baseline	67 (30–72)	45 (22–77)	.55
1 week	90 (30–98)	47 (32–74)	.56
3 months	56 (28–90)	59 (22–78)	>.99
At home (%)			
Baseline	49 (6–63)	35 (13–64)	.84
1 week	84 (5–98)	33 (15–55)	.41
3 months	40 (4–80)	31 (3–66)	>.99
Away from home (%)			
Baseline	91(79–100)	78 (32–97)	.22
1 week	97 (62–99)	91 (28–98)	.49
3 months	92 (86–98)	93 (57–100)	.73

Note: Data are given as median (range). No significant differences at $P < .05$ within and between groups were found.

Table 3. Daily Step Count Overall, at Home, and Away from Home at Baseline and 1 Week and 3 Months After the Intervention

Daily Step Count	Motivational Interviewing Group	Standard Education Group	*P* Value
Overall			
Baseline	10,788 (4,047–15,348)	6,113 (4,400–13,918)	>.99
1 week	9,367 (5,757–12,175)	9,199 (6,430–13,444)	.90
3 months	10,218 (5,656–12,663)	7,458 (2,772–15,809)	>.99
At home			
Baseline	8,200 (1,843–10,279)	3,897 (2,617–9,888)	.55
1 week	6,973 (5,418–8,081)	3,919 (2,607–7,303)	.19
3 months	5,367 (3,298–8,878)	4,229 (1,621–7,523)	>.99
Away from home			
Baseline	2,587 (566–5,887)	2,931 (1,303–6,779)	>.99
1 week	2,536 (1,637–5,201)	4,244 (2,251–9,784)	.34
3 months	3,122 (2,340–7,262)	3,228 (1,151–8,286)	>.99

Note: Data are given as median (range). No significant differences at $P < .05$ within and between groups were found.

type 2 diabetes more than 15 years ago. He was familiar with having foot ulcers on a regular basis since 2007. His overall adherence was 54% at baseline, 35% at 1 week, and 41% at 3 months after the intervention. Adherence at home was very low and did not increase after the intervention: 26%, 28%, and 22%, respectively. When the results of his baseline measurements were discussed, he was surprised that he took so many steps inside his home (8,223 steps per day, 60% of his total number of daily steps). The most notable comment he made was about the utility and perception of his shoes. Although he saw some advantages of wearing the shoes (support and protection), he firmly believed that the shoes were the cause of his ulcers. His

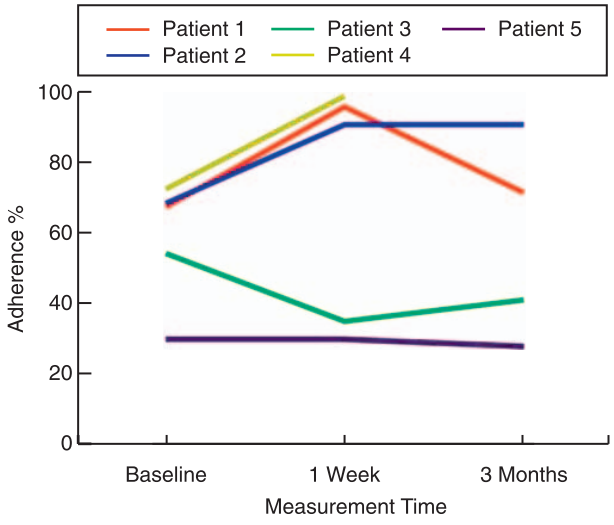

Figure 2. Individual overall footwear adherence for the motivational interviewing group across the three time points.

treating rehabilitation medicine specialist did not agree with him. Moreover, because he perceived his prescription shoes to be heavy and difficult to put on and move around with, and because he reported sitting on the couch much of his time, he considered it easier not to wear them inside. He rated the importance of wearing his shoes more often as a 6.5 on a 10-point scale. His confidence in wearing his shoes more often was not rated. With several reservations, he stated in his intention-to-change plan that he would start wearing his prescribed shoes more often to achieve a level of 75% adherence at home.

Case 4 was a 73-year-old white man with type 2 diabetes who dropped out after the first follow-up measurement due to health reasons. Between the baseline measurement and the motivational interviewing sessions, he received prescribed custom-made shoes that were specially designed as indoor shoes. He experienced less pain while walking and was, therefore, very motivated to wear these indoor shoes.

Case 5 was a white man aged 56 years, unemployed, with type 2 diabetes for more than 15 years. No changes were seen in adherence at home 1 week and 3 months after the intervention. He was not willing to change his shoe-wearing behavior because he felt that this would give noise disturbance for his neighbors.

Feasibility

Assessment and coding by the trainer using the CoSIT-MI of a 20-min part of the first two motivational interviewing sessions showed that basic skills were applied 54 and 49 times by investigators 1 and 2, respectively; and in 13 and

11 instances, respectively, a strategy to elicit change talk was applied. Use of the principles of motivational interviewing was scored on a 7-point scale as a mean of 6 for one investigator and a mean of 5.5 for the other. The study protocol dictated two 45-min sessions of motivational interviewing; however, in four of the five patients the protocol was completed in one session with a mean duration of 53 min.

Most of the protocol items, such as showing the adherence outcomes, providing information on the topic, discussing the reasons for low adherence, and examining readiness to change, were well understood by the participants. Discussing the advantages and disadvantages of both wearing and not wearing their prescribed footwear proved to be difficult at times due to the repetitive nature of the questions asked. We also found some unease in the use of a 10-point scale or percentage improvement score and in making the distinction between the relevance of and the confidence in changing behavior, being new concepts to them. In each patient we were able to complete the protocol by formulating an intention-to-change-plan and setting a new goal in footwear use.

Discussion

The aim of this study was to explore the effects of motivational interviewing compared with standard education on adherence to wearing prescribed footwear and the feasibility of applying motivational interviewing in high-risk patients who have low footwear adherence. When patients are away from home, the study results show that footwear adherence was already high at baseline in both study groups, increased somewhat at 1 week, and remained high over time. Adherence to wearing prescribed footwear does, therefore, not seem to be an issue when patients are away from home. When at home, footwear adherence changed from a median baseline percentage of 49% to 84% at 1 week in the motivational interviewing group. This difference did not reach statistical significance due to the small number of patients tested, but it does represent a relatively large change, which we consider clinically relevant because it passes the threshold of 80% that we use to classify someone as adherent.[6,7] Three months after the intervention, adherence had returned to baseline values (ie, 40%). Only small (a few percent) changes in footwear adherence when at home were seen in the standard education group. Such a clinically relevant, although nonsignificant, short-term improvement in adherence in the intervention group suggests that there may be potential for motivational interviewing in the short-term, also considering that patients were most active inside the house, which confirms earlier data.[7] This needs further study and confirmation in larger trials. The lack of effect found at 3 months should be a focus of further investigation into methods to preserve adherence over time.

The relative increase in adherence in the short-term followed by a decline over time is in line with outcomes of other studies that used motivational interviewing as a method for lifestyle change, as were reviewed by Hettema et al.[11] The 72 studies included in this meta-analysis tested the efficacy of motivational interviewing on outcomes such as alcohol use, smoking, treatment compliance, and diet and exercise. Overall, a rapid positive impact of motivational interviewing was seen, with a gradual decrease in effect over time. Specifically for diabetes, a chronic and complex condition, behavioral change is not easy, as the disease often requires multiple behavioral changes (eg, medication, food intake, exercise).[21] Adherence has been shown to become compromised when several lifestyle behaviors are targeted at the same time.[21,22] Nevertheless, the studies reviewed by Hettema et al also showed that when motivational interviewing was used in addition to standard treatment, the effect seemed to endure over time. This seems in contrast to what we found and may be explained by the fact that most of the standard treatment in the reviewed studies was counseling-style treatment, which uses more one-on-one time with the client than the standard education used in the present study. According to Hettema et al,[11] the persisting effect over time with the addition of motivational interviewing to other counseling-style treatment suggests a synergistic effect. Such a possible synergistic effect needs to be explored in relation to footwear adherence, and this may include boosting sessions of motivational interviewing over time or the additional use of other therapies, such as cognitive behavioral therapy or contingency management interventions.

Cases 1 to 3 represent what may be considered a typical, a successful, and an unsuccessful outcome, respectively. The patient in case 1 showed a short-term increase and a long-term decrease in adherence. Owing to the focus on wearing behavior at home and the information provided, the patient immediately understood the need to wear his shoes more often, without the effect being persistent, maybe because of lack of enduring behavioral mechanisms. The patient in case 2 showed a

successful improvement in footwear adherence from an already quite high adherence level at baseline. Being surprised to find so many steps taken at home, he understood the need to improve and clearly saw the benefits of wearing his prescribed shoes at home. Furthermore, he was very confident that he could change his behavior, which is important for success. The patient in case 3 frequently reulcerated and was clearly unhappy with the weight and comfort of his prescribed shoes. He held the shoes responsible for his foot ulcers. His rating of importance to change was low. Under these circumstances, changing behavior is challenging, effectively creating a paradox: the shoe that is prescribed to protect the foot is perceived as the cause of the problem. The adherence data of the patient in case 4 suggest that custom-made shoes that are prescribed specifically for indoor use, being lighter in weight, clean, and easy to don and doff, may be a good option to resolve low footwear adherence. This option awaits further research. The patient in case 5 seems to show that when no ambivalence is experienced about shoe-wearing behavior, it will be hard to find motivation for change. Thus, as the five cases show, clues seem to be present as to why patients are able or unable to change their shoe-wearing habits. Perception of the benefits of the prescribed footwear seems to play an important role, which corresponds to earlier findings on this topic.[23]

The application of motivational interviewing in the present study seemed to be feasible for the patient group and purpose studied. The investigators were sufficiently trained for enhancing motivation for change in these high-risk diabetic patients using a short, feedback-driven training program. The literature suggests that motivational interviewing can profitably be delivered by a range of professionals with a minimum investment of time in medical care settings.[24] Thus, this can be of interest for podiatric physicians and pedorthists because of their close involvement with prevention and treatment of the diabetic foot. Patients were generally able to understand the protocol and its components, and the investigators were able to complete the protocol in the scheduled time. In most cases, one session seems sufficient to complete the protocol. The discussion of the advantages and disadvantages of wearing and not wearing the prescribed footwear may be simplified by discussing only the advantages and disadvantages of either wearing or not wearing the footwear. And patients may have to be better introduced to specific characteristics of the protocol, such as the use of a 10-point scale and a percentage change scoring system and in understanding the difference between the relevance of and the confidence in change in behavior. Such adaptations to the protocol may result in a better understanding and, therefore, an easier transition to change in behavior.

The patient sample in this study was small because we aimed to assess preliminary effects and the feasibility of using motivational interviewing for the purpose of improving footwear adherence in high-risk diabetic patients, something that has not been done before.[25] The small sample does prevent drawing definite conclusions on efficacy. Despite the small study sample, the data seem to show some clinically meaningful outcomes that correspond to what the literature shows about the effects of motivational interviewing. The results provide relevant input for larger-sized studies. Another limitation was that patient blinding to the goal of the adherence measurement was lost in follow-up measurements because the results at baseline were discussed with the patient during the motivational interviewing sessions. We are not sure whether this influenced patient behavior and study outcome. The lack of change in adherence over time in the standard education group, which did not receive feedback on adherence after baseline, combined with the return of adherence to baseline levels in the motivational interviewing group suggests that such an influence was not the case. The systematic difference in daily step count between groups can partly be explained by the way the data are described, using median and not mean outcomes. Seasonal effects were not present.

Conclusions

Nonsignificant but clinically meaningful short-term positive effects of motivational interviewing on adherence to wearing prescribed custom-made footwear at home, where walking activity is higher than away from home, were found in persons with diabetes who are at high risk for foot ulceration. Such effects were not seen in patients who receive standard education. However, the effects of motivational interviewing do not seem to persevere over time. Additional or adjunctive therapy may be needed to preserve effects on footwear adherence over time. The application of motivational interviewing seems feasible for the purpose and the population of patients studied. These data provide input to larger trials that should be sufficiently powered and include blinding of the patient to the initial adherence assessment, and that should

confirm or refute the findings and hypotheses. Because of their close involvement in the long-term preventive care of this high-risk diabetic patient group, podiatric physicians and pedorthists may be valuable providers of motivational interviewing.

Financial Disclosure: None reported.
Conflict of Interest: None reported.

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