Effect of Weight-Bearing Activity on Foot Ulcer Incidence in People With Diabetic Peripheral Neuropathy: Feet First Randomized Controlled Trial

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Background. Weight-bearing exercise has been contraindicated among people with diabetic peripheral neuropathy (DM+PN). However, recent cohort studies have suggested that daily weight-bearing activity is associated with lower risk for foot ulceration.

Objective. The objective of this study was to determine the effect of a lower-extremity exercise and walking intervention program on weight-bearing activity and foot ulcer incidence in people with DM+PN.

Design. This was an observer-blinded, 12-month randomized controlled trial.

Setting. The settings were physical therapy offices in part 1 of the intervention and the community in part 2 of the intervention.

Participants. The participants were 79 individuals with DM+PN who were randomly assigned either to a control group (n=38) or an intervention group (n=41) group.

Intervention. Intervention components included leg strengthening and balance exercises; a graduated, self-monitored walking program (part 1); and motivational telephone calls every 2 weeks (part 2). Both groups received diabetic foot care education, regular foot care, and 8 sessions with a physical therapist.

Measurements. Total and exercise bout–related daily steps at baseline and at 3, 6, and 12 months were measured by accelerometers. Foot lesions/ulcers were photographed and classified by an independent panel of dermatologists. Use of adequate footwear was monitored.

Results. At 6 months, bout-related daily steps increased 14% from baseline in the intervention group and decreased 6% from baseline in the control group. Although the groups did not differ statistically in the change in total daily steps, at 12 months steps had decreased by 13% in the control group. Foot ulcer rates did not differ significantly between groups.

Conclusion. Promoting weight-bearing activity did not lead to significant increases in foot ulcers. Weight-bearing activity can be considered following adequate assessment and counseling of patients with DM+PN.

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In 2000–2002, approximately 60% of lower-extremity amputations in the United States were diabetes-related, and the majority were preceded by a foot ulcer.[1] During their lifetimes, 40% of the estimated 20.8 million US adults with diabetes mellitus will experience loss of foot sensation.[2,3] Almost all diabetic foot ulcers occur in those with insensate feet due to diabetic peripheral neuropathy (DM+PN).[4,5]

The role of weight-bearing physical activity in the development of diabetic foot ulcers remains poorly understood. Regular participation in moderately intense physical activity (eg, brisk walking) improves glycemic control.[6] Eight-year cardiovascular mortality is 34% lower among people with diabetes who walk 2 hours per week compared with nonwalkers.[7] Therefore, the American Diabetes Association (ADA) recommends at least 30 minutes of daily moderately intense physical activity.[8] However, the ADA recommends that people with DM+PN should limit weight-bearing physical activity because of concerns that it could increase the risk of foot ulcers and amputation.[8,9] Recent descriptive studies, however, suggest that patients with insensate feet who participate in daily weight-bearing activity are at *decreased* risk of foot ulceration compared with those who are less active,[10,11] especially if there is minimal variation in their day-to-day activity pattern.[11,12] A progressive walking program may preserve lower-extremity muscles and make plantar tissue more tolerant to stress and less likely to ulcerate.[13–15] To date, no randomized controlled trial has tested the effect of promoting weight-bearing physical activity on the risk for foot ulceration among people with DM+PN.

As a prelude to further large-scale clinical trials, investigators must develop an effective, safe strategy to increase physical activity among patients with DM+PN. Prior intervention studies have demonstrated that behavioral change programs individually tailored to patients' physical limitations, activity preferences, and readiness to change substantially increase moderately intense activity in older adults.[16,17] However, until now, no one has studied whether interventions of this sort are effective among patients with diabetic complications (such as DM+PN). People with diabetes and insensate feet are one third less active than those with diabetes but intact sensation.[18,19] To investigate these issues, we conducted a randomized controlled trial among adults aged 50 years and older with diabetes mellitus and insensate feet, the "Feet First" study. We hypothesized that the intervention would increase weight-bearing activity significantly more among participants who receive the intervention compared with controls and that this change in activity would not result in increased foot ulcer rates.

Method

Design Overview

Feet First was an observer-blinded, randomized controlled trial of an individually adapted, behavioral change physical activity intervention. Seventy-nine patients with DM+PN were recruited over 18 months and randomly allocated to either an intervention group (n=41) or a control group (n=38). Physical activity, foot function, and foot-related self-care were measured at baseline prior to enrollment and after 3, 6, and 12 months of participation. Foot lesion detection was ongoing throughout the study. In an intention-to-treat analysis, we compared the change in weight-bearing activity from baseline to 3, 6, and 12 months and foot ulcer risk for participants in the intervention and control groups.

Setting and Participants

Patients aged 50 years and over who received diabetes or foot care at primary care, endocrinology, or podiatry practices in central Missouri were invited to join the study. Eligible participants were inactive (did not engage in moderately intense activity more than twice per week for more than 20 minutes per session),[20] had diagnosed type 1 or 2 diabetes mellitus, had absent sensation to 5.07 Semmes-Weinstein monofilament sensation on at least one point at any of 10 sites on each foot,[21] and had loss of vibratory sensation as measured by a biothesiometer (unable to sense <25 V at the great toe).[22] We excluded individuals who lacked telephone access or had medical conditions that might contraindicate exercise.[8] Figure 1 shows contacts, excluded and randomized participants, and those completing the study. Of the 79 participants who were recruited, 1 died of causes unrelated to the study and 2 withdrew early.

Randomization and Intervention

After providing written informed consent, eligible participants who completed baseline measures were randomly allocated to intervention and control groups. Because treatment strategies for early foot lesions could differ among types of clinical sites, randomization was by type of clinical site (specifically, university-affiliated family medicine, university-affiliated endocrinology, VA-affiliated foot clinic, local family medicine and internal medicine practices not affiliated with the university, and out-of-county unaffiliated family medicine and internal medicine practices). Study groups were balanced within each type of site by using randomization blocks of various sizes.[23] Participants returned for a "randomization visit" 2 weeks after their initial visit for baseline measurements and informed consent. Allocation to study groups was concealed by opaque en-

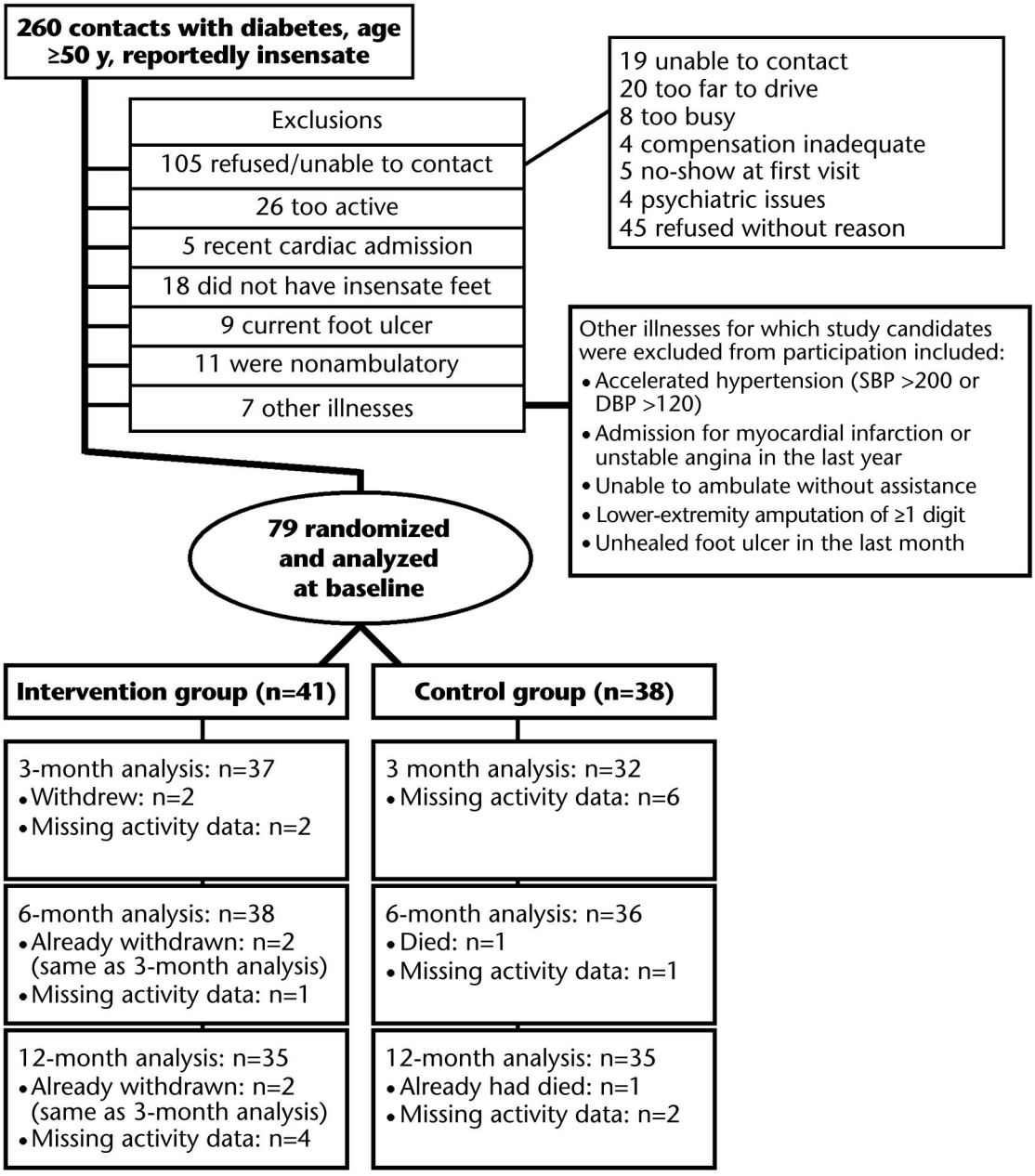

Figure 1.
CONSORT study diagram: recruitment, randomization, and participation. All participants were analyzed as per their allocated group. Participants who withdrew did not provide activity data at or after indicated period of participation. All randomized participants were followed until withdrawal or study completion for foot outcomes. SBP=systolic blood pressure. DBP=diastolic blood pressure.

velopes, which were opened by the study nurse at the randomization visit. Prior to and during this visit, the nurse had no access to information collected from participants at the baseline measurement visit.

The overall aim of the intervention was to encourage participants to gradually increase total daily weight-bearing steps. Based on the predictions of Mueller and Maluf's Physical Stress Theory, we hypothesized that the slow increase in activity would allow foot tissues to adapt to the physical stresses and make them relatively more resistant to ulceration.[14,15] The intervention incorporated components from prior studies

that increased activity in older adults.[20,24–28] It was delivered in 2 parts. During months 1 to 3 (part 1), a physical therapist worked with participants individually via 8 sessions focused on exercises to strengthen lower-extremity muscles and promote balance. These exercises (Appendix) were successful in prior fall-reduction interventions for frail older adults[25–27] and in improving balance in people with peripheral neuropathy.[24] In 3 at-home sessions each week, participants were asked to perform progressively more difficult exercises over 1 hour. After the eighth supervised session, the therapist and study nurse helped each participant to develop a walking plan tailored to his or her personal stage of readiness to change, physical limitations, activity preferences, and social or environmental constraints. The therapist and nurse encouraged participants to increase activity slowly, at minimum adding 100 steps to their daily activities every 2 weeks, using their baseline average activity as the starting point.[8,29] Participants self-monitored their walking using an inexpensive, waist-worn pedometer (Accusplit Eagle 170*) and recorded each day's total steps on an activity log. (This information was used by participants for self-motivation only, not as study data). Participants in the control group received an identical number of visits (n=8) with the therapist at which their feet were examined, but they were not taught leg strengthening or balance exercises or guided to undertake a walking program.

Part 2 (months 4–12) of the intervention was modeled after the Second Community Healthy Activities Model Program for Seniors (CHAMPS II) intervention, which increased moderately intense activity by 50% over 12 months among community-dwelling adults ≥65 years of age.[20] The CHAMPS II intervention was based on social cognitive theory and used motivational techniques that enhanced self-efficacy and readiness to change to promote changes in physical activity via regular telephone calls and workshops.[28,30–32] In the Feet First trial, the project nurse called participants every other week (for a minimum of 10 minutes) to prompt participants to follow their walking plan and assist them in solving related barriers. The nurse received 1 week of intensive training in motivational interviewing techniques from CHAMPS II study staff consultants, with monthly follow-up contact to discuss issues in applying motivational interviewing techniques to specific participants. Control group participants did not have contact with the intervention study nurse after the randomization visit.

All participants were taught foot-related self-care skills, including daily foot examination. They received usual medical care from their own health care providers. Because wearing poorly fitting shoes is a frequent pivotal event preceding a foot ulcer,[5] project staff referred all participants to local orthotists or podiatrists to obtain therapeutic footwear at enrollment. Participants were asked to wear this footwear when standing, walking, or being more active inside and outside their homes.

Outcomes and Follow-up

Observer blinding. Research staff engaged in collecting physical measurements or questionnaire data from participants or tracking other outcomes (ie, foot lesions) were blinded to participants' study group identity (intervention vs. control). These staff did not take part in intervention activities.

Physical activity. At baseline and at 3, 6, and 12 months, each participant was fitted with a StepWatch water-resistant, computerized accelerometer.† Worn on the ankle, the StepWatch reliably counts steps of any intensity every minute without providing feedback to the wearer.[33] It has been validated for people with DM+PN.[14,34] Participants wore the StepWatch continuously when awake (except while bathing) and returned the StepWatch after 14 days. We documented changes in StepWatch-based total daily steps, steps taken in 30-minute exercise bouts, and minutes per week of weight-bearing activity. We defined a "combined physical activity increase" as an increase from baseline in both total daily steps and an increase in bout-related steps. Using the validated Summary of Diabetes Self-Care Activities Scale,[35] participants also reported the number of days per week that they participated in any exercise program at baseline and at 6 and 12 months. Participants also completed a 6-minute walk test at baseline and at 6 and 12 months, which is a safe and valid measure of endurance for moderately intense activities.[36–41] Participants were instructed to walk as fast as they were able for 6 minutes; the distance walked (in feet) constituted the result.

Foot lesions and ulcers. At each study visit (including the 8 initial visits with a physical therapist), study staff examined all surfaces of each participant's feet, including interdigital areas, to identify unreported and occult foot lesions. Therapists also taught participants to inspect their own feet every morning for any evidence of skin breakdown (eg, blisters, abrasions, other skin disruptions). We asked participants to call a dedicated hotline immediately if any of these lesions developed and at least weekly to report the presence or absence of any foot lesions. If a lesion was reported, study staff contacted the participant

* Accusplit, 6120 Stoneridge Mall Rd, Suite 210, Pleasanton, CA 94566.

† OrthoCare Innovations, 700 12th St NW, Suite 700, Washington, DC 20005.

within 24 hours and arranged to examine and photograph the lesion.[42–44] An independent panel of dermatologists who were not otherwise involved in the conduct of the study reviewed the photographs to classify those meeting predetermined criteria for foot lesions and ulcers. Final classification was determined by consensus of panel members. Foot lesions were defined as any disruption of the skin surface (eg, abrasions, lacerations, blisters, macerations) at or below the malleolus; foot ulcers were defined as the subset of these lesions with full-thickness disruption.[45] Any partial-thickness lesion that subsequently became a full-thickness lesion was counted as both a lesion and an ulcer. All lesions or ulcers that occurred at the same time on the same foot were categorized as a single episode. Whenever a foot ulcer or other lesion developed, participants were instructed to limit weight-bearing activity until healing, and study staff helped them make an appointment with a foot care provider.

Other foot-related characteristics measured at baseline included ankle brachial blood pressure index, which was the ratio of supine blood pressure at the brachial artery to that at the dorsalis pedis or posterior tibialis artery, measured using a Koven BiDop-3 doppler stethoscope[‡]; a self-reported foot-related disability score[46]; and history of prior foot ulcers in the year preceding enrollment. Staff inspected the inner and outer surfaces of the participants' shoes for adequacy and wear at each post-enrollment study visit. Thinning (to less than half the thickness of unworn area) or rupture of the insole, outsole, or inner or outer surface of the shoe upper surface indicated excessive wear. Adequate footwear included prescribed or over-the-counter therapeutic footwear and walking or athletic shoes with double-density foam inserts.[47] Study staff advised all participants wearing inadequate footwear at any study visit to consult a local orthotist or podiatrist to obtain adequate footwear.

Demographic and health characteristics included age, sex, current marital status, education, ethnicity, smoking status, type and duration of diabetes mellitus, number of comorbid illnesses, and availability of health insurance. Depressive symptoms were assessed at baseline using the Center for Epidemiologic Studies Depression Scale.[48] Body mass index was calculated as weight (in kilograms)/height squared (in meters squared).

Data Analysis

Intention-to-treat analyses compared the intervention and control groups, regardless of their level of protocol adherence and study participation. Comparisons were 2-sided, and a P value of $<.05$ was considered significant. All analyses were conducted using either SAS version 9.0[§] or Stata version 10.0.[‖]

Physical activity. Primary analyses used a "mixed-effects," repeated-measures regression to investigate changes in weight-bearing activity at 3, 6, and 12 months; activity at baseline was a covariate. This method allows inclusion of participants with some missing data (due to dropout or missed visits).[49] The initial model (model 1) estimated the intervention's effect over the entire study after randomization (between-group effect), whether there was a change in activity within each group from baseline to 3, 6, or 12 months (within-group effect) or whether the change in activity from baseline to 3, 6, or 12 months differed between groups (interaction between groups and months). Because 2 distinct intervention components were delivered by different health care professionals (physical therapists in part 1 and a registered nurse in part 2), model 2 repeated this analysis for outcomes after completion of part 1 only (3 and 6 months). Some participants provided less than 14 days of StepWatch monitoring (eg, if the StepWatch was worn upside-down, it did not register steps). Because estimates of mean steps or minutes based on a larger number of measured days are more precise than those based on a smaller number of days, we weighted mean activity outcome values by the number of days of StepWatch data provided during each monitoring period. We tested whether seasonality at study entry and on subsequent study visits influenced results by including season in regression models; however, it was never significant and did not change outcome estimates by more than 10%. Therefore, season was excluded from final models.

To determine whether adherence to study protocol may have influenced our results, we defined "protocol completers" as participants who: (1) attended more than 50% of the required physical therapy sessions within the required 12-week time period, (2) attended the 3-, 6-, and 12-month study visits within 1 month of the anticipated date, and (3) completed at least 50% of the weekly telephone calls to report lesion outcomes.

Foot outcomes. Incidence rate (IR) of foot lesions and ulcers (each was considered separately) equaled the total number of lesions or ulcers observed for all participants divided by total exposure time in the study for those participants. We estimated

[‡] Koven Technology Inc, 12125 Woodcrest Executive Dr, Suite 320, St. Louis, MO 63141.

[§] SAS Institute. PO Box 8000, Cary, NC 27513.

[‖] Stata LP, 4905 Lakeway Dr, College Station, TX 77845.

Table 1.
Baseline Characteristics by Group[a]

Characteristic	Control Group (n=38)	Intervention Group (n=41)
Demographic/behavioral		
Age (y), mean (SD)	64.8 (9.4)	66.6 (10.4)
Married (%)	60	67
Women (%)	53	47
Nonwhite (%)	8	7
Nonsmokers (%)	87	95
Years of education, mean (SD)	15 (2.9)	14.1 (3.0)
No health insurance (%)	0	3
Health		
Type 2 diabetes (%)	92	95
Years since diabetes diagnosis, mean (SD)	11.2 (8.5)	10.8 (8.3)
No. of comorbid diseases, mean (SD)	2.3 (1.6)	1.8 (1.5)
Cardiovascular disease (%)	26	32
Joint pain in lower limbs (%)	71	73
Cancer (%)	21	19
Respiratory disease (chronic bronchitis or asthma) (%)	25	20
BMI (SD)	37.2 (8)	35.9 (8.2)
CESD depression score (>16=depressed)	10.2	10.0
Physical activity (estimated, weighted by no. days data provided)		
No. of days performing exercise program during last 7 days, mean (SD)	1.3 (1.8)	0.8 (1.5)
Foot-related characteristics		
No. of foot ulcers in past year, mean (SD)	0.6 (1.5)	0.37 (1.3)
Ankle brachial blood pressure index (1.0=normal) (SD)	1.01 (0.1)	1.05 (0.1)
Adequate shoes worn (%)	54	62
Foot-related disability score (range=0–81), mean (SD)	25.6 (18)	25.3 (20)

[a] No characteristics were significant at $P<.05$. BMI=body mass index, CESD=Center for Epidemiologic Studies Depression Scale.[48]

incidence rate ratios ($IR_{intervention}/IR_{control}$) and 95% confidence intervals (CIs) to determine whether either study group was at significantly increased risk. We used the GENMOD procedure in SAS to perform Poisson regression with categorical predictor variables (eg, group) as well as with continuous covariates (eg, time enrolled). We tested these regression models for departure from the Poisson distribution (which assumes that each foot ulcer outcome occurred independent of any prior ulcers). Analyses consider foot lesions, total ulcers, and weight-bearing ulcers for the first 6 months and for the full 12-month study. These outcomes were monitored by a Data Safety and Monitoring Board, which was responsible for halting the study if the incidence rate of foot ulcers in one group significantly exceeded that in the other group.

Sample size. Taking advantage of other prior work,[14,19,50] sample size computations were based on the anticipated change in the number of steps per day (hereafter referred to as "daily steps"). Maluf and Mueller[14] found that people with diabetes and insensate feet, on average, took 3,908 daily steps (SD=1,487). We assumed that participants in our control group would take a similar number of daily steps at baseline and that the standard deviation of the change in total daily steps would be similar to that in the study by Maluf and Mueller. The study had 96% power to detect a 25% difference between groups in the change in total daily steps between baseline and 3, 6, or 12 months (a change of 977 daily steps, half the change in activity achieved in the original CHAMPS II study, proportionally).[20] The study also had 80% power to detect a doubling of the incidence rate of foot lesions comparing the intervention and control groups after 12 months of participation. This assumed an incidence rate equal to 0.75 lesions per person-year in the control group (the rate observed in a randomized trial in a similar population).[5]

Role of the Funding Source

The study was funded by the Robert Wood Johnson Foundation, which approved the study design but did not direct the study team regarding conduct or analysis of the study.

Results

Table 1 presents baseline characteristics for the 79 participants. The groups did not differ at baseline with respect to demographic, health or foot-related characteristics, or weight-bearing activity. The average age of participants was 66 years, 51% were women, and participants had an average of 15 years of education. Mean diabetes duration exceeded 11 years, and 93% of the participants had one or more serious comorbidities.

Table 2.
Estimated Weight-Bearing Physical Activity, by Months in Study (Based on Stepwatch3 Computerized Pedometer) (Weighted by Number of Days of Data Provided per Period)

Activity Parameter	Baseline (n=79)	3 Months (n=69)	6 Months (n=74)	12 Months (n=70)
Total daily steps				
Control group, mean (SEM)	3,350 (247)	3,059 (237)	3,009 (237)	2,921 (243)‡
Intervention group, mean (SEM)	3,335 (246)	3,237 (223)	3,417 (233)	3,183 (240)
Pooled SD (baseline)	1,656.5			
ES (95% CI)[a]		0.11 (−0.37,0.58)	0.25 (−0.21,0.70)	0.16 (−0.31,0.63)
Steps taken in 30-min bouts				
Control group, mean (SEM)	495 (29)	456 (29)	465 (38)	477 (37)
Intervention group, mean (SEM)	482 (29)	506 (27)	548 (37)‡,§,††	510 (37)*
Pooled SD (baseline)	194.2			
ES (95% CI)		0.26 (−0.22,0.73)	0.43 (−0.03,0.88)	0.17 (−0.30,0.64)
Ambulatory minutes per week				
Control group, mean (SEM)	590 (49)	526 (47)	511 (45)‡	500 (45)‡
Intervention group, mean (SEM)	570 (49)	560 (44)	579 (44)	549 (45)
Pooled SD (baseline)	33.5			
ES (95% CI)		0.10 (−0.37,0.58)	0.20 (−0.25,0.66)	0.15 (−0.32,0.62)
6-min walk test (distance in feet)				
Control group, mean (SEM)	1,103 (57)	Not measured at this point in study	1,061 (73)	1,012 (82)
Intervention group, mean (SEM)	1,096 (57)		1,025 (72)	996 (82)
Pooled SD (baseline)	354.4			
ES (95% CI)			−0.10 (−0.56,0.36)	−0.04 (−0.52,0.43)
Days per week participating in structured exercise program				
Control group, median (25th–75th percentile)	0 (0–1.5)	Not measured at this point in study	1.5 (0–2)	1.5 (0–3)
Intervention group, median (25th–75th percentile)	0 (0–2)		3.0 (0–5)†	2.5 (0–5)
Overall difference between groups in change in activity from baseline pooled group effect (3, 6, and 12 months combined) (model 1): *$P<.05$ **$P<.01$ ***$P<.001$		Difference between groups in activity at indicated month (model 1): †$P<.05$ ††$P<.01$ †††$P<.001$		
Difference from baseline activity within group (model 1): ‡$P<.05$ ‡‡$P<.01$ ‡‡‡$P<.001$		Difference between groups in change in activity from baseline at 6 months (model 2): §$P<.05$ §§$P<.01$ §§§$P<.001$		

[a] Effect size (ES) was calculated for each comparison and expresses the difference in means independent of the outcome measure's metric. ES= (intervention group postintervention mean after 3, 6, or 12 months of participation minus control group mean)/pooled baseline standard deviation. CI=confidence interval.

Table 2 presents estimated weight-bearing activity based on StepWatch measurements. In both the pooled analysis including all data collection points (model 1) and the analysis after part 1 of the intervention only (model 2), the change in total daily steps did not differ significantly between study groups; however, total steps decreased by 13% over the 12-month study within the control group.

Steps taken during 30-minute exercise bouts increased 14% from baseline to 6 months in the intervention group, whereas they decreased 6% in the control group. There was a difference between groups in this outcome at both 6 and 12 months (model 1) and in the change between baseline and completion of

part 1 of the intervention (model 2). There was no difference between groups in the change (in minutes) of ambulatory activity per week from baseline to 3, 6, or 12 months (model 1 or 2), although it decreased by 15% between baseline and 12 months within the control group. There was no difference in the change in 6-minute walk test distances between baseline and 6 or 12 months (model 1 or 2), either between groups or within either group. The change in the number of exercise days per week from baseline to 6 months differed significantly between groups. Reported number of days participating in structured exercise programs increased from 0 days per week in both groups at baseline to 3 days per week in the intervention group and 1.5 days in the control group by 6 months; however, by 12 months, the number of exercise days per week no longer differed between groups (Tab. 2).

The range of increase in total daily steps for participants with a "combined physical activity increase" (an increase in both total steps and bout-related steps between baseline and 6 months) was 96 (minimum) to 3,610 (maximum) steps daily, with a median increase of 898 total steps daily (25th percentile=513, 75th percentile=1,762). These same participants had an increase in bout-related steps ranging from 10 to 1,027 steps during the most active 30 minutes of the day, with a median increase of 73 steps (25th percentile=39, 75th percentile=332 steps). The "combined physical activity increase" occurred more often among intervention group participants (n=16, 39%) than among control group participants (n=7, 18%) after 6 months of participation (odds ratio [OR]=2.83, 95% CI=1.01–7.96), although this did not hold true by 12 months (intervention group: n=13 [32%], control group: n=10 [26%], OR=1.3, 95% CI=0.48–3.48). This outcome was not associated with any other demographic, health, or foot-related baseline characteristic.

Mean follow-up was 392 days (SD=92) in the intervention group and 403 days (SD=68) in the control group but did not differ between groups. With respect to protocol adherence, at 6 months, only 18 (45%) participants in the intervention group and 13 participants (35%) in the control group qualified as "completers" through timely achievement of more than 50% of all study protocol elements (χ^2=0.78, P=.38). By 12 months, this number had fallen to 7 (18%) participants in the intervention and 9 (24%) in the control group (χ^2=0.45, P=.50). Nonetheless, when we excluded from the analysis participants who were not fully adherent, none of the regression estimates for any activity outcome varied from the intent-to-treat analysis by more than 10%. Figure 2 shows changes in mean activity for the intervention and control groups, with 95% CIs comparing all participants with completers at baseline and at 3, 6 and 12 months.

A total of 57 foot lesions were detected during the 12-month study. Nine lesions resulted from self-inflicted trauma during self-care (eg, cutting a toe while attempting to cut a toenail) and were excluded from further analysis. Of the remaining 48 lesions, 18 were full-thickness ulcers (9 in each study group, overall incidence=17%). Given that 58% of the sample had no history of foot ulcers (predicted annual incidence=4.5%) and that 42% had a history of foot ulcers (predicted annual incidence=31.7%), the predicted annual incidence of foot ulcers in this sample was 15.9%.[51] Ulcers were generally small: only 1 ulcer in the intervention group and 4 ulcers in the control group were greater than 1 cm^2 in surface area (χ^2=2.62, P=.10). All ulcers healed except one on the foot of a participant who died due to causes unrelated to the study. Ulcer duration was 74 days (SD=49) in the intervention group and 51.5 days (SD=43) in the control group (one-way F test=1.25, df=1, P=.27). None of the ulcers required hospitalization for infection, and none led to amputation or Charcot arthropathy. Total foot ulcer and foot lesion incidence rates did not differ significantly between groups after 6 or 12 months of participation (Tab. 3). Ulcer rates on plantar weight-bearing areas did not differ significantly between the intervention and control groups at any point during the study. Plantar weight-bearing ulcer rates were the same during the first 6 months of follow-up (both groups=0.05 ulcers/person-year-at-risk). For the full 12-month study, the rate of weight-bearing ulcers was 0.02 ulcers/person-year-at-risk in the intervention group and 0.12 ulcers/person-year-at-risk in the control group. Shoe adequacy and wear did not differ between groups at any point in the study (data not shown in the tables).

There was one nonulcerative adverse event possibly related to a specific component of the intervention. One participant in the intervention group with previously undiagnosed osteoporosis sustained a proximal phalangeal great toe fracture attributed to a leg strengthening exercise in part 1 of the intervention (raising up on toes). To avoid the possibility that this fracture could become neuropathic (Charcot), the participant was excused from further exercises of this sort, but still undertook a limited walking program after the fracture healed.

Discussion

In this randomized controlled trial, we found that the intervention increased weight-bearing, bout-related physical activity. This type of activity increased most notably between

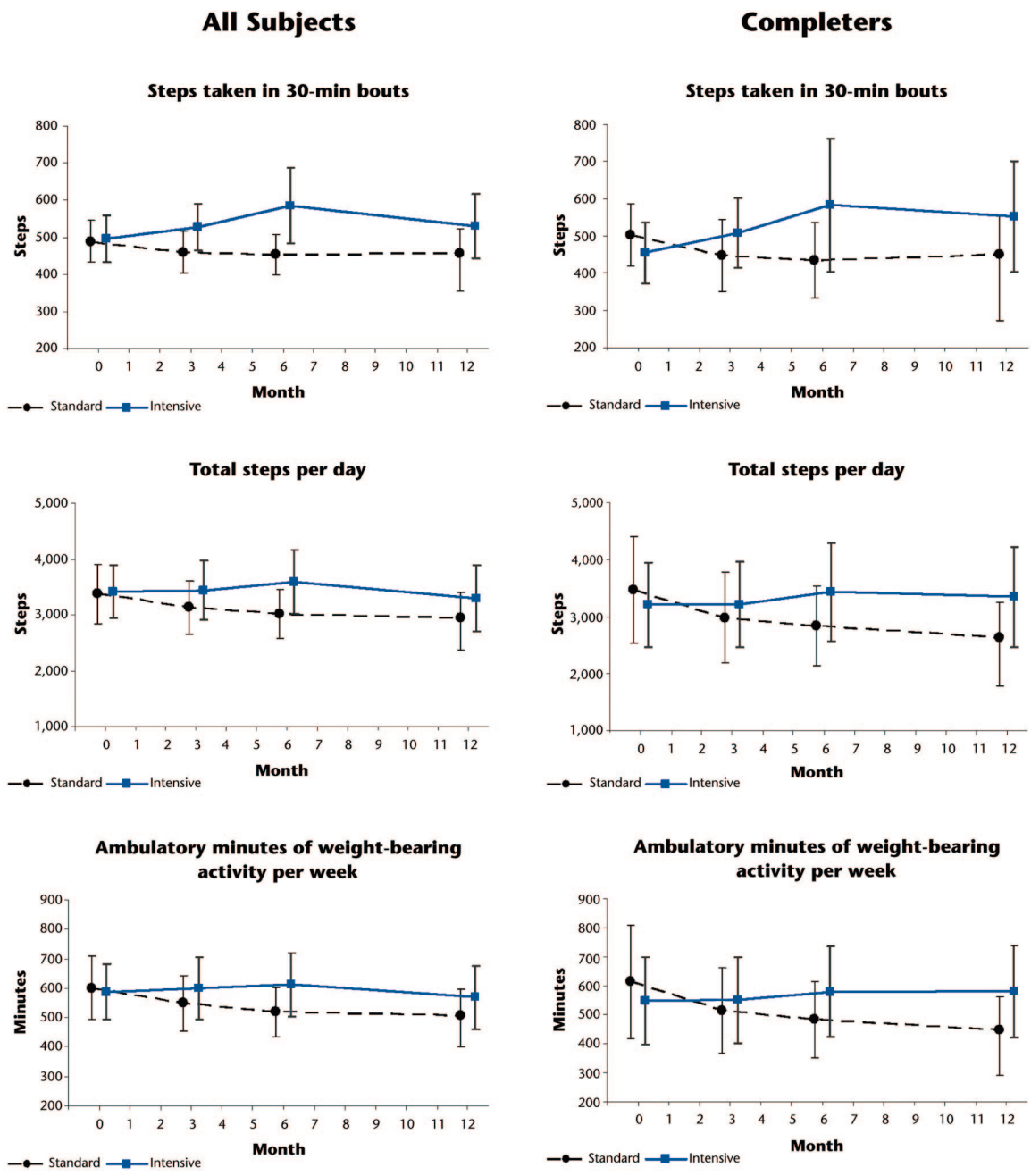

Figure 2.
Step activity monitor findings for intervention and control groups and study completers: means with 95% confidence limits (actual values).

baseline and 6 months, after participants had completed part 1 of the intervention (physical therapist visits). Although there was no difference between groups in the change in total daily steps from baseline to any subsequent point in the study, participants in the control group decreased total steps by 13% over 12 months. Participants in the intervention group were about 3 times more likely to increase both total steps and bout-related steps by 6 months compared with participants in the control group. Participation in structured exercise sessions also increased more among participants in the intervention group (from 0 to 3 days per week) compared with those in the control group (0 to 1.5 days per week) by 6 months. These changes regressed toward baseline during the last 6 months of study participation.

Table 3.
Foot Ulcer and Lesion Analysis

Lesion Parameters	First 6 Months of Study			12 Months (Whole Study)		
	No. of Lesions	Incidence Rate	Rate Ratio (95% CI)[a]	No. of Lesions	Incidence Rate	Rate Ratio (95% CI)
All lesions (ignoring multiplicity of lesions per episode)						
Intervention group	22	1.12 lesions/pyar[b]	1.52 (0.78–2.97)	27	0.63 lesions/pyar	1.24 (0.70–2.19)
Control group	14	0.74 lesions/pyar		21	0.51 lesions/pyar	
Lesion episodes (accounting for multiple lesions per episode)						
Intervention group	21	1.07 lesions/pyar	1.45 (0.74–2.85)	26	0.61 lesions/pyar	1.32 (0.73–2.38)
Control group	14	0.74 lesions/pyar		19	0.46 lesions/pyar	
All full-thickness ulcers (ignoring multiplicity of lesions/episode)						
Intervention group	8	0.41 ulcers/pyar	1.93 (0.58–6.42)	9	0.21 ulcers/pyar	0.96 (0.38–2.42)
Control group	4	0.21 ulcers/pyar		9	0.22 ulcers/pyar	
Full-thickness ulcer episodes (accounting for multiple lesions/episode)						
Intervention group	7	0.36 ulcers/pyar	1.69 (0.50–5.78)	8	0.19 ulcers/pyar	1.1 (0.40–3.03)
Control group	4	0.21 ulcers/pyar		7	0.17 ulcers/pyar	
Weight-bearing full-thickness plantar ulcers (ignoring multiplicity of lesions/episode)						
Intervention group	1	0.05 ulcers/pyar	0.97 (0.06–15.5)	1	0.02 ulcers/pyar	0.19 (0.02–1.64)
Control group	1	0.05 ulcers/pyar		5	0.12 ulcers/pyar	
Weight-bearing full-thickness plantar ulcer episodes (accounting for multiplicity of lesions/episode)						
Intervention group	1	0.05 ulcers/pyar	0.97 (0.06–15.5)	1	0.02 ulcers/pyar	0.32 (0.03–3.08)
Control group	1	0.05 ulcers/pyar		3	0.07 ulcers/pyar	

[a] CI=confidence interval.
[b] pyar=person-year-at-risk.

Consistent with our hypothesis, we found that foot lesion and plantar foot ulcer rates did not differ significantly between study groups at any point in the study. Because participants were closely supervised and quickly referred to foot care providers upon ulceration, no ulcer progressed to infection, amputation, or Charcot arthropathy. These findings suggest that an intervention promoting weight-bearing activity such as the Feet First intervention is not harmful to the feet of people with DM+PN. The overall incidence of ulceration (17%) was similar to that predicted in prior studies among similar patients with similar characteristics and comorbidities.[51,52]

Participants in this study achieved only modest increases in activity. Recent meta-analyses of interventions promoting physical activity in people with chronic illnesses, including diabetes, showed that behavioral strategies such as giving participants daily step prescriptions, asking participants to monitor their daily steps, and using personal trainers to supervise them carefully as they increased activity produced larger effect sizes than studies without these components; however, cognitive interventions (such as the motivational strategies used in part 2 of our intervention) were less effective at increasing activity.[17,53] Future interventions investigating the effect of weight-bearing activity among people with DM+PN should provide a more intense program that provides patients with specific daily step goals and closely supervises their increase in activity.

The Feet First intervention also helped participants in the intervention group to maintain their baseline number of total daily steps, whereas in the control group, participants' total steps decreased consistently over the data collection period, declining 13% over 1 year. Given the dose-response increase in all-cause and cardiovascular mortality in people with diabetes associated with progressively greater inactivity,[54,55] preventing a decline in physical activity of this magnitude is an important achievement in this population apart from the effect of the intervention on foot ulcer risk. Although we did not find that the Feet First intervention increased total daily steps, it did help participants increase steps taken in bouts. In a recent randomized trial of participants with type 2 diabetes who were sedentary, Richardson and colleagues[56] found that providing participants with a targeted number of daily steps was

more effective than providing a targeted number of minutes of activity per day in increasing total daily steps.

Although Stewart and colleagues[20] found a 50% increase in exercise behavior in the original CHAMPS II study, the basis for part 2 of our intervention, only 7% of their sample had diabetes. Comorbidity in our sample was much higher than among the CHAMPS II study participants. In the current study, comorbidity was equally distributed between the intervention and control groups, so any exercise limitations arising from comorbidity probably affected both groups similarly.

ADA recommendations that people with DM+PN should limit weight-bearing activity are based on research on the effect of weight-bearing activity on insensate feet that was first conducted by Brand and colleagues, who found that repetitive mechanical stimulation of anesthetized rats' footpads led to skin ulceration. In those experiments, footpads that received 10,000 daily repetitions ulcerated within 10 days; however, footpads that received slightly less daily stimulation (8,000 steps per day) for 5 days per week never ulcerated.[57] A number of cohort studies subsequently demonstrated an association between high plantar foot pressures and increased diabetic foot ulcer risk.[58–61] Together, these studies led to the belief that repetitive stimulation to areas of increased pressure on an insensate foot during walking would further increase foot ulcer risk.[9] (Also see the related article by Mueller et al[62] investigating the physical stresses contributing to neuropathic ulcers in this issue.)

Surprisingly, Maluf and Mueller[14] recently found that people with DM+PN and a history of foot ulcers took 46% fewer daily steps and had 41% less cumulative daily forefoot tissue stress (plantar pressure multiplied by daily steps) than people without ulcers, suggesting that those who ulcerate are less tolerant of daily stress and that a progressive increase in weight-bearing activity may lead to plantar tissue hypertrophy and reduced ulcer risk. LeMaster and colleagues[10] also found that among people with prior diabetic foot ulcers, those who participated in weight-bearing activity at least 7.5 hours per day were at 80% less risk of reulceration compared with those who were weight bearing less than 4.5 hours per day. Similarly, Armstrong and colleagues[11] found that among people with DM+PN monitored continuously for 25 weeks, those who ulcerated were significantly less active than those who did not, although variability in activity was higher among those who ulcerated. Although the current study did not show evidence that weight-bearing activity reduced foot ulcer risk, neither did it show evidence that foot ulcer risk increased. Additional studies using interventions with higher intensity are needed to help determine whether neuropathic skin and feet can adapt positively to increasing stress levels.

This study had a number of potential limitations. First, the study was designed primarily to detect differences in physical activity between groups rather than differences in foot ulcer incidence. We did this realizing that any inferences regarding the *effect* of physical activity on foot ulcer risk are dependent on the change in weight-bearing physical activity. The incidence rate ratio we observed for the full 12-month study for full-thickness ulcers and ulcer episodes was essentially equal to 1, indicating no significant or clinically important differences between groups; however, CIs were wide. Wide CIs indicate that a clinically important difference cannot be excluded with high probability. Subsequent studies should be designed to detect differences in important but rarer outcomes, such as the incidence of foot ulcers on weight-bearing areas of the foot.

Second, the Step Watch accelerometer measures only minutes of activity taken during stepping. Time spent standing immobile is not recorded; however, we did not observe any significant differences between groups in time spent inactive.

Third, participants in the control group did not receive motivational calls from the study nurse and may not have been as engaged in the study as participants in the intervention group. This could have led to reduced reporting of minor foot lesions by controls; however, we did not find any significant difference in protocol adherence between groups.

Fourth, the high level of close participant follow-up in the study helped us to detect foot lesions at an earlier stage than would likely have been possible during routine clinical care. This may have reduced the power of the study to detect a difference between groups in foot ulcer risk because lesions were treated successfully before they developed into full-thickness skin ulcers.

Finally, to reduce participant burden, we did not monitor participants' physical activity or cumulative plantar tissue stress continuously throughout the study. This may have allowed us to miss key changes in activity that occurred just prior to the development of foot lesions. Future studies should consider continuously monitoring participants' activity or foot stress (and the relationship between activity patterns and foot lesions) throughout study participation.

Conclusion

This study showed that participants in the Feet First intervention group achieved a modest increase in activity, with no increase in foot lesions, compared with those in the control group. We recommend additional research to further investigate current guidelines and close supervision for people with DM+PN as they attempt to increase their weight-bearing activity and make changes in this important self-management behavior.

All authors provided concept/idea/research design, writing, and fund procurement. Dr LeMaster, Dr Reiber, and Dr Madsen provided data analysis. Dr LeMaster provided project management and subjects. Dr Reiber provided Seattle-based facilities/equipment and institutional liaisons. Dr Mueller, Dr Reiber, Dr Mehr, Dr Madsen, and Dr Conn provided consultation (including review of manuscript before submission).

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The study was approved by the University of Missouri–Columbia Health Sciences and University of Washington institutional review boards and by the research and development committees at the Harry S Truman Memorial Veterans' Hospital in Columbia, Missouri, and the VA Puget Sound Health Care System in Seattle, Washington.

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Appendix.

Intervention Program Part 1: Leg Strengthening and Balance Exercise[a]

Level 1	Level 2	Level 3	Level 4
1. One-leg stand, with both hands[26] 2. Hip circle (30° from body)[26] 3. Arm circles (30° from body)[26] 4. Knee lifts while seated, arms to side[26] 5. While sitting on an inflatable exercise ball, catch a beach ball[25] 6. Toe raises, both feet (set of 10 raises, 3 sets), with one hand, if necessary[24]	1. One-leg stand, with one hand[26] 2. Walk on exercise mat with arms extended[26] 3. Step sideways, with both hands (10 steps, 4 times)[26,27] 4. March while seated[26] 5. Knee lifts while seated, arms across chest[26] 6. Heel stand (lifting the toe to balance on the heel), with one hand, on both feet[27] 7. Walk in a figure-of-8, twice, with one hand[27] 8. Walk backward, with one hand 9. Ankle inversion and eversion (shift center of mass laterally), with both hands, both feet (set of 10, 2 sets)[24]	1. One-leg stand, with no hands[26] 2. Walk on exercise mat with arms folded[26] 3. Step sideways, with one hand (10 steps, 4 times) 4. Standing, cross legs at ankles[26] 5. Standing leg lift (bend leg, lift to horizontal)[26] 6. Heel stand[24,27] 7. Tandem walk, with one hand (10 steps, 4 times)[27] 8. Walk in a figure-of-8, twice, with no hands[27] 9. Step over irregular objects 10. Toe raises, on one foot, with one hand, if necessary (set of 10, 2 sets)	1. Standing arm/leg march[26] 2. Crossover walk[26] 3. Tandem walk, with no hands (10 steps, 4 times) 4. Heel-toe walk, with no hands (10 steps, 4 times)[27] 5. Step sideways, with no hands (10 steps, 4 times)[27] 6. Walk backward, with no hands[27] 7. Toe-tap (as per Berg Balance Scale, item #12), with no hands 8. Ankle inversion and eversion, with one hand always, on one foot (1 set of 10)[24] 9. Balance on one foot (10 s, 3 tries per session)[24]

[a] The number of repetitions represents the goal for each exercise at the indicated stage. Participants started with one set and progressed no faster than 1 level per week for any given exercise. "Both hands" means holding a stable object with both hands (eg, a wall, an assistant's hand) while performing the maneuver; "one hand" means holding on with only one hand. "Both feet" means performing the maneuver while standing on both feet; "one foot" means performing the maneuver while standing on one foot. All participants practiced the "both hands" version of each exercise prior to attempting the maneuver without holding a steady object. All maneuvers were practiced initially under the supervision of the physical therapist, prior to practicing the maneuver at home. The above maneuvers are drawn from the referenced intervention studies.