Accepted Manuscript

Weight-bearing versus non-weight-bearing exercise for persons with diabetes and peripheral neuropathy: A randomized controlled trial

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PII: S0003-9993(12)01284-1

DOI: 10.1016/j.apmr.2012.12.015

Reference: YAPMR 55308

To appear in: *ARCHIVES OF PHYSICAL MEDICINE AND REHABILITATION*

Received Date: 7 August 2012

Revised Date: 19 November 2012

Accepted Date: 20 December 2012

Please cite this article as: Mueller MJ, Tuttle LJ, LeMaster JW, Strube MJ, McGill JB, Hastings MK, Sinacore DR, Weight-bearing versus non-weight-bearing exercise for persons with diabetes and peripheral neuropathy: A randomized controlled trial, *ARCHIVES OF PHYSICAL MEDICINE AND REHABILITATION* (2013), doi: 10.1016/j.apmr.2012.12.015.

Title Page

Running Head: Exercise for limitations from neuropathy

Title: Weight-bearing versus non-weight-bearing exercise for persons with diabetes and peripheral neuropathy: A randomized controlled trial

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Financial Support: NIH NCMRR R21 HD058938 (Mueller), T32 HD007434-17 (Mueller, Tuttle), NSMRC R24HD650837, NIH UL1 RR024992, Diabetes Research Training Center 5 P60 DK20579, and scholarships from the Foundation for Physical Therapy (Tuttle).

Acknowledgments: Cindi Inman, Kay Bohnert, Kshamata Shah, Ellen Frye, Erin McKeague and Molly Burns provided valuable assistance with participant testing, interventions, data entry, and data analysis.

The authors deny any **conflict of interest** present in this work.

Financial Disclosure: We certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on us or on any organization with which we are associated AND, if applicable, we certify that all financial and material support for this research (eg, NIH or NHS grants) and work are clearly identified in the title page of the manuscript.

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Reprints are not available.

Clinical Trial Registration Number: NCT00763087

Abstract: Weight-bearing versus non-weight-bearing exercise for persons with diabetes and peripheral neuropathy: A randomized controlled trial

Objective. To determine the effects of weight-bearing (WB) versus non weight-bearing (NWB) exercise for persons with diabetes and peripheral neuropathy (DM+PN).

Design. A randomized controlled clinical trial with evaluations at baseline and after intervention.

Setting. A university based physical therapy research clinic.

Participants with DM+PN (64.5±12.5 years old; body mass index = 35.5±7.3) were randomly assigned to WB (n=15) and NWB (n= 14) exercise groups. All participants (100%) completed the intervention and follow-up evaluations.

Intervention consisted of group specific progressive balance, flexibility, strengthening, and aerobic exercise conducted sitting or lying (NWB) or standing and walking (WB) three times a week for 12 weeks.

Main Outcome Measures were six minute walk distance (SMW) and daily step counts. Secondary outcome measures represented domains across the International Classification of Functioning, Disability and Health.

Results. The WB group showed greater gains than the NWB group over time in SMW and average daily step count ($p<0.05$). The mean and 95% confidence intervals (CI) between group difference over time was 29 (6 to 51) meters for the SMW distance and 1178 (150 to 2205) steps for average daily step count. The NWB group showed greater improvements than the WB group over time in hemoglobin A1c values ($p<0.05$).

Conclusions. The results of this study indicate the ability of this population with chronic disease to increase SMW distance and daily step count with a WB exercise program compared to a NWB exercise program.

Key Words: Exercise, diabetes, peripheral neuropathy

List of Abbreviations

DM	Diabetes Mellitus
PN	Peripheral Neuropathy
SMW	Six minute walk test
FAAM	Foot and Ankle Ability Measure
BDI	Beck Depression Inventory
WB	Weight-Bearing
NWB	Non Weight-Bearing

Persons with diabetes mellitus (DM) and lower extremity pathology such as peripheral neuropathy (PN) have an almost 3-fold increase in risk of limited mobility compared to those having neither.[1] The most frequently reported mobility limitations are related to an inability to walk a quarter mile and to climb 10 steps without resting.[1] Gregg et al, and Volpato et al, report substantial functional limitations, especially in weight-bearing activities (i.e., limitations in walking 2-3 blocks) in women with DM and relate this limitation to PN.[2,3]

Although considerable research has documented the benefits of moderately intense physical activity (i.e., brisk walking) for those with DM,[4-6] little research has been conducted investigating the effects of exercise among people with DM+PN, perhaps because of investigator concerns regarding exercise-related injury to participants' insensitive feet and skepticism that exercise could be beneficial. The most common contributor for diabetic plantar ulcers is high plantar stresses in the presence of sensory neuropathy and foot deformity.[7, 8] Historically, people with DM+PN have been advised to avoid weight-bearing activity,[9] but inactivity may contribute

to the de-conditioning of the skin and lowering tolerance for weight-bearing activities.[10] Several studies provide evidence to support the hypothesis that people with DM+PN who are *less* active are at *greater* risk for skin breakdown than those who are more active.[11-13] In addition, the "Feet First" randomized controlled trial demonstrated that people with DM+PN in a community-based, relatively low-intensity intervention, can increase bout-related daily steps (14% after 6 months) without an increase in skin breakdown.[14]

The current study provided a more intensive and progressive intervention than the Feet First[14] program using supervised weight-bearing (WB; e.g. treadmill walking) and non weight-bearing (NWB; e.g. stationary bicycle ergometer) exercise approaches. The purpose of this prospective randomized controlled clinical trial was to determine the effect of a WB exercise program compared to a NWB exercise program on the primary outcome measures of six minute walk distance (SMW) and daily step counts (steps/day). Secondary outcome measures represented domains across the International Classification of Functioning, Disability and Health. We hypothesized that the WB exercise would show greater improvements in primary outcomes compared to the NWB exercise group.

METHODS

Informed consent was obtained from all participants who agreed to participate with a form approved by the institutional review board.

Inclusion Criteria: Participants were required to have Type 2 DM, PN (inability to sense the 5.07 Semmes Weinstein monofilament on at least one spot on the plantar foot and inability to sense vibration at the plantar great toe from a biothesiometer at < 25 volts), have a step count

2,000-9,000 steps/day, currently exercising < 3 x/week; <20 min/session, and have approval of their primary physician to participate in the study.

Exclusion Criteria: Participants were excluded who weighed greater than 300 pounds (scanner weight limit used in a different portion of study), had a severe foot deformity that would require custom therapeutic footwear, or any co-morbidity or medication that would interfere with ability to exercise according to the current American Diabetes Association guidelines.[9]

Sample Size and Recruitment

Recruitment began in 2009 and was terminated in 2011. Since the natural tendency in this population is for walking ability to decline,[14] we thought a 20% increase in average daily step count would be meaningful. Armstrong et al reported this population takes 4548$\pm$779[15] steps per day. Assuming the NWB group would not show a difference in average daily step count, a 20% (910 steps) between group difference would result in an effect size equal to 1.15 standard deviation units. With an estimated alpha=0.05, power=0.80, and an effect size = 1.15 standard deviation units, an *a priori* power analysis estimated a recruitment sample size of 14 in each of the 2 exercise groups for the primary outcome variables. Although the *a priori* estimated sample size needed for average daily step count was 14 in each group, we had planned to recruit 32 subjects in each group because of possible attrition and smaller estimated effect sizes for secondary outcome variables. Attrition was low, but recruiting participants who met the criteria and were willing to exercise was challenging (see CONSORT - Figure 1) and we stopped recruitment with the number of subjects described in this study.

Participants were recruited from our data base of previous participants, the Washington University School of Medicine Research Participant Registry, cable television commercials, a newspaper story, and recruitment posters displayed in a Diabetes Treatment Center and on area

commuter trains. Participants were given ten dollars cash at the completion of every visit to cover travel expenses and serve as an incentive for attendance, and an additional fifty dollars for completing final testing.

Design and Randomization

Participants were randomized into 2 groups (WB, NWB) using a prearranged schedule generated by the statistician (MJS) using a computer program. Allocation was concealed to all except the research coordinator who entered subjects into the study. Participant characteristics are summarized in Table 1; there were 15 and 14 participants in the WB and NWB groups respectively. There were no significant differences between groups in any of the characteristics ($p>0.05$).

Interventions

All participants exercised, as able, in one hour group sessions (1-4 participants/group) 3 times per week for 12 weeks that were supervised by a physical therapist and an assistant. Duration and intensity were matched between groups as closely as possible. Target heart rate was intended to be 60-70% of age-predicted maximum, and activity was adjusted to stay within those limits using a heart rate monitor and a Rating of Perceived Exertion between 11-13 on a 6-20 scale.[9] Intensity for all exercises was individualized with the intent to exceed their routine physical stress level (based on daily community-based step counts), and therefore incur positive adaptations to physical stress, but not exceed their estimated intensity for injury.[10, 14, 16-19] Exercise participation was modified, postponed, or stopped based on the current guidelines of the American Diabetes Association.[9] The exercise sessions began with 20 minutes of group specific flexibility and stretching exercises (Appendix 1) followed by strengthening exercises (Appendix 2) and aerobic exercise (Appendix 3).

To help avoid skin injury, all exercises included in this study, except for the heel rise, had peak plantar pressures that were less than or equal to those during level walking.[20] Furthermore, the physical therapist and the participant each performed a visual inspection of the participant's feet and footwear, and recorded foot skin temperature using a handheld infrared thermometer[a] before and after each session as described previously.[21] Initially, participants were not allowed to continue exercising if pre-test temperature differences were > 4 degrees when compared across feet,[21] but because there was a high rate (20% on first 26 participants) of false positives (i.e., temperature differences of > 4 degrees Fahrenheit despite no visible lesion, redness, or progression of lesion regardless of activity level), the study data safety monitoring committee agreed to discontinue use of the temperature monitoring as part of required precautions. Participants wore their own athletic or walking shoes that passed a screen for excessive wear, fit (length and width), accommodation of bony deformities, and areas of high pressure. [22] Participants with footwear that did not meet the criteria were helped to select appropriate fitting shoes.

Weight Bearing Exercise Program

Baseline duration of walking was individually calculated based on participants' own average daily step count collected over 7 days using the Step Watch Activity Monitor[b]. Participants were instructed to increase their center-based step count every 2 weeks by 24% on the 3 days that they participated in the exercise program, thus resulting in an average increase in their daily step count by 10% during that 2 weeks period (See Appendix 3). The WB group conducted most exercises in a standing position, used body weight for resistance exercises (i.e., sit to stand, stair climbing), and a treadmill or walking around a large circular hallway for aerobic exercise.

Non-weight Bearing Exercise Program

The NWB group conducted all exercises in a sitting or lying position. They used elastic resistance bands[c] with increasing stiffness for load resistance and a stationary upright or recumbent cycle ergometer for aerobic exercise. Duration of stationary bicycle time started with the time predicted from the participants' average daily step counts and was increased every 2 weeks in a similar fashion to the WB group (Appendix 3).

Outcome Measurements

Full testing occurred immediately before and after the 12 week intervention period. All outcome measures were collected and analyzed by a tester blinded to group assignment except for the post treatment six minute walk test which was conducted by a physical therapist who also provided some treatment. All measures were collected in a Physical Therapy laboratory except the blood draws for Hemoglobin A1c, which were collected at a hospital outpatient lab.

The Six Minute Walk Test (SMW) was performed as a measure of physical function and walking endurance. The participants walked in a hallway and were told that the goal was to walk as far as possible in 6 minutes. The test has been validated in obese adults.[23] A meaningful change in score is considered to be greater than 20 meters (65.6 feet).[24]

Step activity monitoring: Average daily step count was estimated using the StepWatch activity monitor[b], an accelerometer attached to the participant's ankle that provides a time stamped recording of strides (1 stride equals 2 steps). We used an average steps/day for a 7 day period collected over 14 days; a reliable and valid measure of overall activity levels.[11, 26] For a day to be included, the activity had to be apparent for at least 8 hours a day, and at least 1 weekend day was included in the 7 day average.

Secondary Outcome Measures: The Foot and Ankle Ability Measure (FAAM) is a self-report measure of physical function and investigates the participant's perception of 26 activities of daily living (i.e. walking on even ground and up hills). We report the participant's overall perception (0-100%) of foot and ankle ability.[25] The Beck Depression Inventory®—II (BDI®–II) was used to assess impact of the exercise program on negative affect.[26] Higher scores correspond to higher levels of depression. A 9 item Physical Performance Test (PPT) was used to measure functional limitations.[27] Hemoglobin A1c was used as an indicator of blood glucose control while fat free mass was measured using dual-energy x-ray absorptiometry[d] (DXA) as an indicator of body composition.[28] Right plantar flexion peak torque was measured sitting using a Biodex isokinetic dynamometer[e] with an angular velocity of 60 degrees per second as an indicator of ankle muscle strength impairment. Right dorsiflexion range of motion was measured prone with the knee extended as a measure of ankle joint impairments.[29, 30]

Skin lesions on the lower leg were monitored to document the safety of the interventions. All surfaces of the foot were photographed before and after treatment using a digital camera and stored electronically. If the treating therapist observed any break in the skin, they completed a "wound documentation form" describing size (width, length, depth), location, apparent reason for the wound, and the action taken. Pictures and forms were sent to 2 blinded adjudicators (and a third if there was disagreement). Wounds were graded as a "lesion" (superficial injury such as abrasion, laceration, blister, or maceration) or an ulcer (full thickness skin wound through the dermis).

A follow-up survey was sent to participants a mean time of 15.5 (5.3) months after they completed participation in their intervention to understand better their perspective of the value of the exercise program and their current exercise / skin monitoring habits.

Data Analysis

Statistical analysis on an intention-to-treat basis was performed using the Statistical Package for the Social Sciences software[f]; alpha was set to .05. A two group (WB, NWB) by two time (pre and post testing) repeated measures analysis of variance (ANOVA) was used.[31] Analyses focused on between group differences over time; i.e., whether the repeated-measures ANOVA for group by time interaction was significant. Mean between and within group differences over time with a 95% confidence interval are reported.

RESULTS

All 29 participants completed the 12 week intervention. The WB and NWB groups attended 83.4 (11.0) %, and 83.3 (10.8) % of total exercise sessions, respectively. Results are presented in Table 2.

The WB group showed greater gains than the NWB group over time (significant interactions) in the primary outcomes of SMW distance and average daily step count ($p<.05$). The mean (95% CI) between group difference over time was 29 (6 to 51) meters for the SMW distance and 1178 (150 to 2205) steps for average daily step count.

The NWB group showed greater improvements than the WB group over time (significant interaction) in hemoglobin A1c values ($p<.05$). The mean (95% CI) between group difference over time was 0.50 (0.03 to 0.96) %. There were no other between group over time differences in outcome measures.

Adverse Events: There were a total of 13 lesions and 4 ulcers observed during the study (Table 3). One person in the WB group had a calf strain during treadmill walking, but was able to continue to exercise with a lower intensity (shorter time on treadmill, fewer heel raises) and the

strain resolved within one week. Three of 14 participants in the NWB group modified their stationary cycle aerobic activity a total of 3 occasions, and 6 of the 15 participants in the WB group modified (12 occasions) or deferred (8 occasions) their treadmill aerobic training because of pain.

Follow-up Questionnaire: We received 22 completed surveys a mean time of 15.5 (5.3) months after completion of their intervention (Table 4). During this follow-up period, one participant had died in each group unrelated to the study and the 5 others did not respond to mailings or phone calls. In brief, 86% reported feeling better as a result of their participation in the exercise program and 41% reported they were still exercising 3-7 days a week.

DISCUSSION

Consistent with our hypothesis, the WB exercise group showed greater gains over time compared to the NWB exercise group in the primary outcomes of SMW distance and average daily step count (Table 2). While one would expect WB exercise to have a greater impact on walking ability than NWB exercise, it is only recently that this population has been encouraged to walk,[5,9] and the effects of a progressive walking program are mostly unknown. These improvements are somewhat greater than those achieved by the "Feet First" study intervention, which reported no change in the SMW distance, no change in total daily steps, and a 14% increase in average daily steps in 30 minutes after the 6 month community intervention program.[14] The methods and exercise intervention in the current study were more intensive (3 times per week supervised by a physical therapist vs 8 supervised sessions combined with home exercise 3 times per week) but over a shorter duration (12 weeks vs 6 months) than those used in the "Feet First" study. While the overall activity level is still low, these improvements are

important given that the natural tendency for activity in this group is to decline (13% decrease in daily step count over one year in "Feet First" control group).[14]

There were benefits observed in the NWB group not observed in WB group. The NWB group showed an improvement in their hemoglobin A1c values, similar to another recent study investigating the effect of exercise on people with DM+PN.[32] Post hoc analysis on actual time spent performing aerobic exercise indicated that the NWB group started at a higher duration (14.4±3.9 vs 11.4±2.9 minutes, P=0.027) and ended at a higher duration (26.6±6.5 vs 18.7±4.9 minutes, P=0.032) of aerobic exercise. This increased volume of exercise may have been enough to help improve hemoglobin A1c values. Those in the NWB group also had fewer complaints of lower extremity musculoskeletal pain during aerobic exercise than the WB group. Consistent with other recent recommendations,[5, 14, 32] we believe people with DM+PN who do not have severe foot deformity or open ulcers should be given the choice to exercise in a WB or NWB capacity, and that exercise should be tailored to match their personal goals.

The lesions that occurred during this study generally were small, healed quickly (Table 3), and consistent with recent studies of those with DM+PN showing minimal training related adverse events.[14,32] Importantly, 3 of the 4 ulcers occurred in the 5 participants with a history of a previous ulcer. Reports on annual population-based incidence (new onset) of diabetic foot ulcers range between 1.0% and 4.1%,[33] but in those with a history of skin breakdown, ulcers reoccur at a rate of 20-70% a year.[34, 35] Additional research is needed to determine the value and safety of WB and NWB exercise for people with a history of ulcer and for those with severe foot deformity.[36] Research also is needed to determine if these positive results can be translated into community settings.

We believe there were a number of reasons for the low dropout rate and high adherence rate in this study. Participants were provided ten dollars at each visit to cover transportation expenses and provide an incentive for adherence. While not consistent with clinical care, this approach appeared to motivate adherence substantially. In addition, each person's exercise program was individually tailored to their current ability and activity level. The overall exercise program was considered moderate and participants generally (82%) thought this intensity level was "just right" (Table 4). Furthermore, participants were under close supervision of their skin and vital signs using a small group (1-4) approach, which seemed to foster a sense of safety, community, and accountability.

Study Limitations

The study had a small number of participants and was not powered adequately to determine group differences in secondary outcomes. Between group differences over time for the primary variables, although significant, had a wide 95% CI with the potential for a low treatment effect. We believe there is potential for greater improvement with a higher exercise intensity and /or duration. The aerobic exercise duration, especially for the WB group, was not as much as we had hoped. We underestimated number of additional steps needed for a 10% increase each week because we based the increase on time duration of walking at a step rate of 100 steps per minute (Appendix 3), but participants walked slower than that.[37] This study also had limited follow-up. We focused on the controlled, short-term effects of moderate exercise in an understudied, high-risk population, but longer term follow-up with a larger sample size and greater exercise duration is needed. Furthermore, we used a blinded tester for most measures, but we should have used a blinded tester for the SMW test. We acknowledge this limitation but contend any bias was minimized by using highly consistent and standardized instructions. . Finally, these participants

were selected from a much broader range of people with DM+PN (Figure 1) and results can be generalized only to those meeting the inclusion and exclusion criteria of this study.

CONCLUSIONS

People in the WB exercise group showed greater gains in daily step count and SMW distance compared to those in the NWB exercise group, while those in the NWB group showed greater improvements in hemoglobin A1c values compared to those in the WB group. Additional research is required to determine whether higher intensity/duration and a combination of WB and NWB exercise would improve outcomes further without compromising safety, and if results can be translated to a community setting.

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Suppliers

a. Xilas Medical Inc, San Antonio, Texas

b. Orthocare Innovations, 840 Research Parkway, Suite 200,Oklahoma City, OK 73104

c. Theraband; Hygenic Corporation, 1245 Home Ave, Akron, Ohio 44310

d. Hologic, Waltham, MA 02451

e. biodex Medical Systems, 20 Ramsey Rd, Shirley, New York 11967

f. SPSS version 16.0; SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, Illinois 60606

Figure Legend

Figure 1: CONSORT Figure

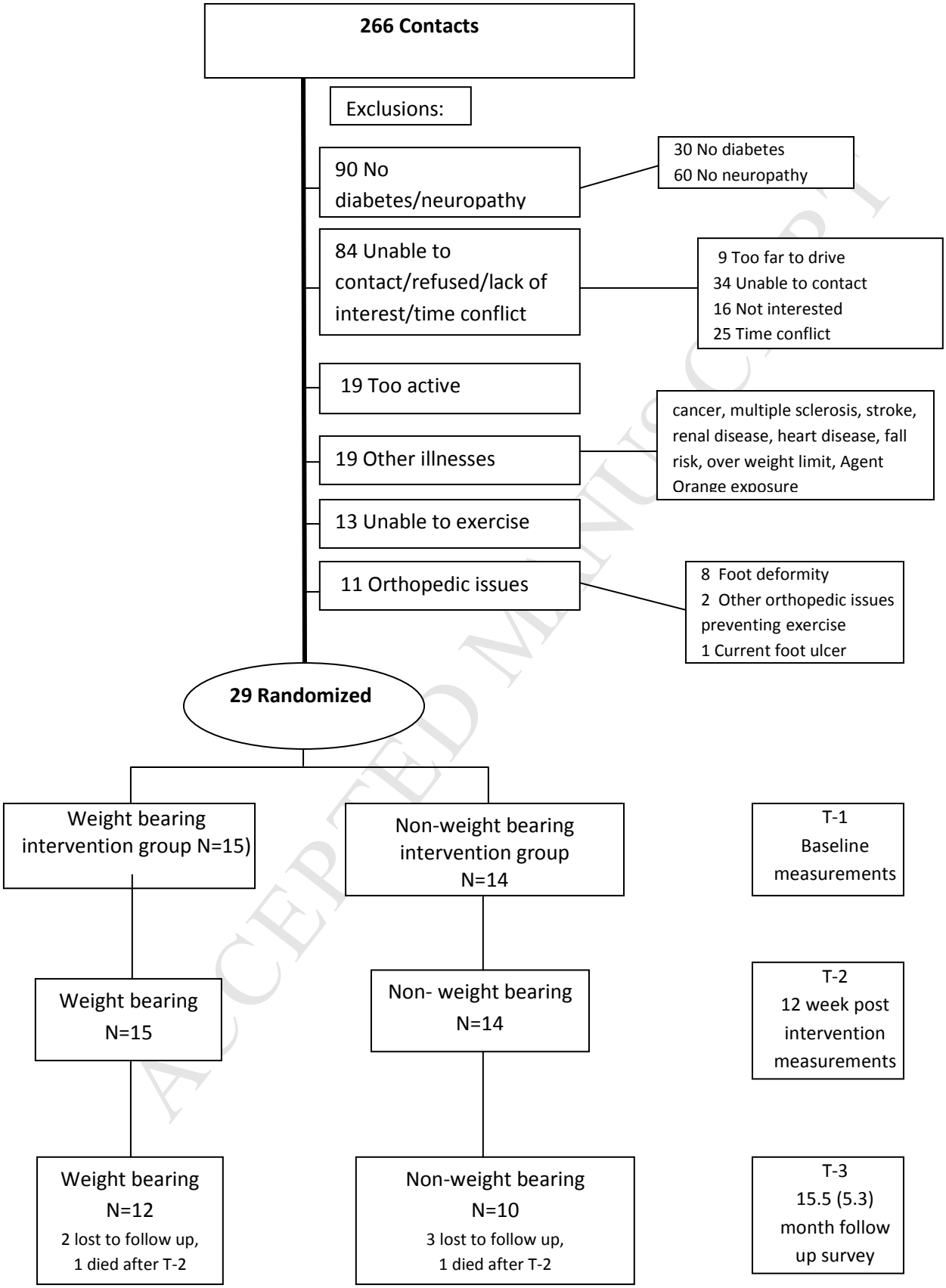

Table 1: Participant Characteristics

	WB Group	NWB Group
Number of participants	15	14
Male/female	10/5	7/7
Age (yrs)	65.2 (12.8)	63.9 (12.5)
Duration of DM (yrs)	11.4 (8.1)	13.4 (5.4)
Body mass index (kg/m^2)	36.8 (6.3)	33.1 (7.3)
Neuropathy – biothesiometer (V)	44.1 (8.6)	45.0 (8.7)
Number of co morbidities	2.3 (1.7)	1.7 (1.2)
Cardiac procedures/ Conditions	11	6
Hypertension	11	11
History of cancer	4	3
History of foot ulcer	2	2

Values are given as mean and the standard deviation. No difference between groups in any measures ($p>0.05$).

Table 2: Summary of Results of Outcome Variables

Variable	Group	Pre-Test Value Mean (SD)	Post-Test Value Mean (SD)	Mean Within-Group Time Difference (95% CI)	Mean Between Group Difference, Change over Time (95% CI)	Group by Time Interaction P Value
Primary Variables						
Six Minute Walk	WB	378 (72)	404 (78)	27 (11 to 42)		
Distance (meters)	NWB	418 (106)	417 (112)	-2 (-18 to 14)	29 (6 to 51)	0.014
Average Daily Step	WB	4909 (1398)	5593 (1449)	685 (-29 to 1399)		
Count (steps)	NWB	6571 (2186)	6078 (2023)	-493 (-1232 to 246)	1178 (150 to 2205)	0.026
Secondary Variables						
Overall Perception,	WB	73.0 (21.6)	83.7 (12.5)	10.7 (1.8 to 19.5)		
FAAM (0-100; %)	NWB	79.5 (16.8)	85.2 (13.7)	5.7 (-3.8 to 15.2)	5.0 (-8.0 to 17.9)	NS
Beck Depression	WB	7.7 (5.8)	5.8 (4.8)	-1.9 (-4.1 to 0.3)		
Inventory (0-63)	NWB	7.9 (7.1)	5.3 (3.8)	-2.6 (-4.9 to -0.4)	0.8 (-2.4 to 4.0)	NS
Physical Performance	WB	28.1 (4.6)	29.5 (4.9)	1.4 (0.04 to 2.8)		
Test (9 item; 36 max)	NWB	27.1 (4.6)	28.7 (4.2)	1.6 (0.2 to 3.0)	-0.2 (-2.1 to 1.8)	NS
Glycated Hemoglobin	WB	6.9 (1.3)	7.0 (1.3)	0.1 (-0.2 to 0.4)		
(HbA1c, %)	NWB	7.8 (2.1)	7.4 (1.6)	-0.4 (-0.8 to -0.1)	0.50 (0.03 to 0.96)	0.037
Fat Free Mass	WB	63.5 (11.6)	63.3 (11.5)	-0.2 (-1.2 to 0.8)		
DXA (kgs)	NWB	57.3 (11.6)	57.9 (11.9)	0.6 (-0.5 to 1.6)	-0.8 (-2.2 to .6)	NS

R Plantar flexion	WB	38.0 (20.3)	42.8 (24.2)	4.8 (-2.6 to 12.1)		
Peak Torque (N/m)	NWB	38.4 (12.6)	39.1 (12.1)	0.7 (-6.9 to 8.2)	4.1 (-6.5 to 14.6)	NS
R Dorsiflexion KE	WB	3.6 (6.9)	7.7 (4.2)	4.1 (1.7 to 6.5)		
range of motion (^{o})	NWB	3.1 (4.7)	5.5 (5.2)	2.4 (-0.1 to 4.9)	1.7 (-1.8 to 5.2)	NS

Table 3: Characterizations of Skin Breakdown: Lesions and Ulcers

	LESIONS by group and location on foot (13 lesions in 12 participants)			
GROUP	**Total number of lesions**	**Number of participants with a lesion**	**No. on wt-bearing surface of foot**	**No. on Non wt-bearing surface of foot**
Weight-bearing	7	7	2	5
Non-wt-bearing	6	5	0	6

All lesions were superficial (i.e., not full thickness wound) 2-5mm; except for 3 superficial "scratches". Average time to heal was 8.8 (7.2) days.

	ULCERS by group and location on foot (4 ulcers on 3 participants)			
GROUP	**Total number of ulcers/participants**	**Number of participants with an ulcer**	**No. on wt-bearing surface of foot**	**No. on non wt-bearing surface of foot**
Weight-bearing	1	1	1	0
Non-wt-bearing	3	2	3	0

Average size of the 4 ulcers was 12.5 mm by 16mm by 2mm deep. Average time to heal was 20.7 days (15.8) days except for one ulcer that was not healed at end of intervention.

Data above are for descriptive purposes, as the study was not powered to detect differences in lesions or ulcers between groups.

Table 4: Follow-up Questionnaire (Percent answered per questionnaires returned)

	NWB (N=10)	WB (N=12)	Total (N=22)
Overall, do you think you feel better, worse, or about the same because of your participation in the exercise program?			
a.) Better	90	83	86
b.) Worse	0	8	5
c.) No different	10	8	9
In your opinion, how strenuous was the exercise program?			
a.) Too easy	20	17	18
b.) Just Right	80	83	82
c.) Too difficult	0	0	0
What were your thoughts of the exercise program in this study? (circle all that apply)			
a.) Too far away	0	8	5
b.) Fun	50	92	73
c.) Time consuming (tedious)	0	0	0
d.) Just the right amount of time	60	58	59
e.) Exercise times were convenient	80	92	86
f.) Exercise times not convenient	0	0	0
g.) Confidence building	60	83	73
h.) Positive lifestyle changes	50	58	55
Would you participate in another exercise program?			
a.) Yes	100	58	77
b.) No	0	0	0
c.) Not sure	0	42	23
How often are you exercising?			
a.) 7 days/wk	20	8.	14
b.) 3-6 days/wk	20	33.	27
c.) 1-3 days/wk	40	33.	36
d.) Less than 1 day/wk	10	0.	5
e.) I never exercise for at least 20 min at a time	10	25.	18
How often do you check your feet?			
a.) 7 days/wk	40	67	55
b.) 3-6 days/wk	30	25	27
c.) 1-3 days/wk	20	8	14
d.) I never check my feet	10	0	5

Do you check your feet more, less, or about the same amount compared to before you were in the study?

a.)	More	60	58	59
b.)	Less	10	0	5
c.)	Same	30	33	32

Since your participation, have you had any skin breakdown or injuries on your feet?

a.)	Yes	0	8*	5
b.)	No	100	92	95

*Participant reports burning skin on feet from soaking feet in water that was too hot.