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FOOTFIT Physical Activity mHealth Intervention for Minimally Ambulatory Individuals With Venous Leg Ulcers

A Randomized Controlled Trial

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ABSTRACT

PURPOSE: The purpose of this study was to investigate the use of an mHealth application (app), self-management physical activity intervention FOOTFIT with an added patient-provider connectivity feature (FOOTFIT+), that was designed to strengthen the lower extremities of minimally ambulatory individuals with venous leg ulcers (VLUs).

DESIGN: Randomized controlled trial.

SUBJECTS AND SETTING: Twenty-four adults 18 years and older with VLUs being treated in 2 wound clinics in the Southeastern United States participated in this study.

METHODS: Preliminary estimates and 95% confidence intervals for the medians of short-term functional impacts on foot function, strength, ankle range of motion, walking capacity, depression, and physical functioning were obtained pre- and postassessment after the 6-week intervention trial.

RESULTS: There were negligible changes in either group for foot function. It is noted that both groups experienced substantial foot and ankle impairment at baseline. The greatest improvement in range of motion was noted in the FOOTFIT group for dorsiflexion of the right ankle (4.6 ± 5.22 lb/in^2 over baseline) whereas strength decreased in both ankles for dorsiflexion and plantar flexion in the FOOTFIT+ group. No improvements were noted in walking distance or physical health for FOOTFIT (slight decrease −2.9 ± 5.6) and FOOTFIT+ (slight increase 3.0 ± 6.6) during the 6-week study period.

CONCLUSIONS: In a minimally ambulatory population with VLUs, our mHealth FOOTFIT intervention composed of progressive exercise "boosts" demonstrated minimal short-term effects. We recommend engagement with the app for a longer period to determine longer-term outcomes of lower extremity function.

KEY WORDS: Exercise, mHealth, Physical activity, Randomized controlled trial, Venous leg ulcers.

INTRODUCTION

Venous disease and diabetes mellitus, with and without neuropathy, are associated with high functional deficits of the lower extremity, including the foot. Foot and lower leg musculoskeletal impairments negatively affect foot mechanics, making it difficult to walk, stand, or climb stairs, and place individuals at high risk for falls.[1,2] The incidence of altered foot mechanics increases in the presence of venous leg or plantar/diabetic foot ulcers (VLU/DFU), especially in patients wearing foot offloading or compression devices.[3] The most negatively affected mechanical properties among individuals with leg and foot ulcers are calf muscle pump impairment, reduced ankle strength and range of motion, particularly in dorsiflexion and plantar flexion.[4] Reduced range of motion of the ankle is associated with decreased foot and calf muscle contractility and higher muscle deoxygenation, which both contribute to the deteriorating condition of the lower legs, substantially restricting mobility, and altering wound healing.[5,6]

Exercise interventions for individuals with lower extremity ulcers is recommended to improve calf muscle pump function and leg conditioning. Data from multiple systematic reviews and studies of different types of physical activity/exercise programs that incorporated stretching and strengthening training suggest ankle-foot function improved in patients with venous disease, diabetic neuropathy, and leg and foot ulcers.[7-12] Thus, when managing patients with lower extremity ulcers, it is important to consider foot-ankle strength and range of motion as part of the treatment plan. However, minimally ambulatory

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patients with ulcers are often excluded from both studies and exercise/physical activity programs; thus, it is unclear whether there are benefits to be gained for this population by participation in an exercise regimen aimed to strengthen the lower extremities.

To address this gap, we investigated whether initial findings support the use of an mHealth, self-managed intervention to strengthen the lower extremities of minimally ambulatory patients with VLUs. We refer to this "short" foot fitness training program as "FOOTFIT"; the program incorporates our evidence-based conditioning activities for lower leg function (CALF) exercises, coupled with a foot-based accelerometer (BEAT) and a smartphone mobile application (app) developed by our team.[13-15] In this article, we report preliminary estimates and confidence intervals of the short-term functional effects on foot strength and range of motion, and walking capacity.

METHODS

In a 6-week pilot study of adults with VLUs, patients were recruited from 2 wound centers in the Southeast United States. Inclusion criteria were 18 years or older, impaired functional mobility (operationally defined as not being able to walk 100 ft without the need to stop or rest), not currently participating in physical therapy or activity, anticipated to receive at least 6 weeks of weekly wound care, and an ankle brachial index between 0.8 and 1.3 (no arterial insufficiency). Individuals were excluded if they had comorbid conditions such as stroke or severe arthritis that limited ankle function, an ulcer from another cause (arterial, surgical, or traumatic ulcer), or cognitive impairment determined by less than 2 recalled words or abnormal clock drawing on the MiniCog test[16] administered at baseline. Participants were initially approached by the study wound physicians (D.M.C. and M.B.H. consultants) to gauge study interest, and were referred to the study coordinator (M.P.) for prescreening. If found eligible on prescreening, participants were scheduled for the first baseline study visit where they were consented and screened per the inclusion/exclusion criteria described earlier. Study measures were then collected. Eligible participants were randomized 1:1 to either the FOOTFIT or FOOTFIT+ interventions, and provided with detailed study instruction. FOOTFIT comprised 6-week progressive exercises composed of toe and foot taps, dorsiflexion and plantar flexion movements, and lower extremity kickouts, and ankle twirls/circles (CALF), a foot-based Bluetooth-enabled triaxial accelerometer and app (BEAT). In contrast, the FOOTFIT+ app included an additional patient-provider communication feature. Both the FOOTFIT and FOOTFIT+ apps provided automated educational/motivational messages and user reports. Foot movement on the VLU-affected leg was tracked by BEAT. After study instruction, participants were required to demonstrate proficiency in access to and use of the app. Study visits occurred at baseline and at 6 weeks.

Study procedures were reviewed and approved by the Medical University of South Carolina Institutional Review Board, Charleston, South Carolina (#00043451), and registered with ClinicalTrials.gov NCT02632695 on December 17, 2015. Written informed consent was obtained for all patients.

Instruments

Demographic and pertinent medical information included age, sex, race/ethnicity, health and medication history, comorbid conditions, ulcer history, education level, residency, and other variables. Outcomes included estimates of short-term functional impact measures and their variability: range of motion, strength, function, walking, depression, overall well-being, ankle, and calf circumference. Foot range of motion was measured with a goniometer and reported in degrees (°) with a goal of an increase in 5°. Foot strength was measured with a dynamometer and reported as pounds per square inch (lb/in^2) with a goal of an increase of 10 lb/in^2. Overall ankle and foot function was measured with the 21-item Foot and Ankle Ability Measure (FAAM) (intraclass correlation coefficient [ICC] = 0.89), with the goal of an increase in 10% function.[17] Scores were calculated by adding all the completed responses on a 5-point Likert scale (0 to 4), then multiplying by 4; lower scores reflect greater disability.[18] Walking capacity was measured with the 6-minute walk test (ICC = 0.94) and reported as distance in feet walked over 6-minute time with a goal of an increase of 30 ft beyond baseline.[19,20] Participants were assessed for depression via the 15-item Geriatric Depression Scale (GDS) (ICC = 0.89); participants were determined to have depression if the GDS score was more than 5.[21,22] Overall functional health and well-being was measured with the 12-Item Short-Form Health Survey (SF-12), which screens for physical (SF Physical Component Summary [PCS]; ICC = 0.79) and mental (SF Mental Component Summary [MCS]; ICC = 0.74) component summary health domains.[23,24] Both components are scored using norm-based methods and standardized with a mean of 50 and a standard deviation of 10, which are comparable to component scores for the general US population. Scores range from 0 to 100; higher scores represent better physical and mental health.[25] Poorer mental and physical health has been shown to be negatively associated with engagement in physical activity.[26] Ankle and calf circumferences were measured with a standard cloth tape measure and reported in centimeters (cm) to show any changes in edema, which is common in the lower legs affected by VLUs. Data were collected preintervention at the baseline visit and at postintervention during the last visit week.

Sample Size Determination and Allocation

Sample size was based on the feasibility aim for pragmatic reasons, where a total of 24 participants were considered appropriate to determine feasibility for recruitment, adherence, and other outcomes (paper currently under review). We followed recommendations of Eldridge and colleagues[25] in their extension to the CONSORT 2010 statement to randomized pilot and feasibility trials.[27] We did not carry out hypothesis testing procedures; rather, we measured descriptive statistics along with a 95% confidence interval for the median; given the small sample size we did not assume that data were normally distributed. A computer-generated random number schema was developed by the statistician (M.M., fourth author) in which group allocation was concealed and revealed to the study coordinator (M.P.) after baseline data were collected. Participants were then informed of allocation to either FOOTFIT or FOOTFIT+.

Statistical Analysis

For measures of pain, foot strength/range of motion, and walking within the FOOTFIT and FOOTFIT+ groups, pre- to postintervention change was estimated via 95% confidence intervals for the medians. The goal was to obtain estimates of the variability of planned future efficacy outcomes. Data were entered on a password-protected web-based data management system Research Electronic Data Capture (REDCap) and analyzed using SAS Software Version 9.4 (SAS Statistical Institute, Cary, North Carolina).

RESULTS

The Figure shows the participant CONSORT flow diagram. The demographic and clinical baseline features of both FOOTFIT (n = 12) and FOOTFIT+ (n = 12) groups are summarized in Table 1. The medians at baseline, after the 6-week intervention, differences in medians within and between groups, and their 95% confidence intervals for the FOOTFIT and FOOTFIT+ groups for clinical outcomes are shown for ankle range of motion, strength, foot function, and walking distance (Table 2), ankle and calf circumference (Table 3), and depression and overall physical and mental health (Table 4). The tables include collected baseline and week 6 data for enrolled participants. While benchmarks were set a priori for changes in clinical outcomes, we aimed to determine whether any changes demonstrated potential clinical relevance due to the small sample size and short intervention period of this trial. The 5° increase in benchmark set for range of motion measured with the goniometer for dorsiflexion, plantar flexion, inversion, and eversion was not achieved except for dorsiflexion of the left ankle in the FOOTFIT group (6.5 ± 11.7 over baseline). There were no clinically meaningful changes noted in strength anticipated to improve by 10 lb/in^2 for dorsiflexion and plantar flexion. The greatest improvement was noted in the FOOTFIT group for dorsiflexion of the right ankle (4.6 ± 5.22 lb/in^2 over baseline), whereas strength decreased in both ankles for dorsiflexion and plantar flexion in the FOOTFIT+ group. Ankle and calf circumferences measured with a tape measure showed no clinically relevant changes during the 6-week study. The 10% improvement benchmark for foot and ankle function measured with FAAM was not achieved. It is noted that both groups experienced substantial foot and ankle impairment at baseline. Walking distance was slightly higher in the FOOTFIT group at baseline (600 ft ± 594) compared to FOOTFIT+ (527 ± 512 ft). Neither group met the benchmark set for increased walking 30 ft beyond baseline.

We also measured depression via the GDS; scores demonstrated both groups screened below the cutoff of 5 for depression at baseline and after the 6-week intervention. Overall physical (PCS) and mental health (MCS) assessed with the SF-12 showed participants PCS scores were well below the mean score of 50 reported in the literature, suggesting participants experienced poorer physical health than most others in

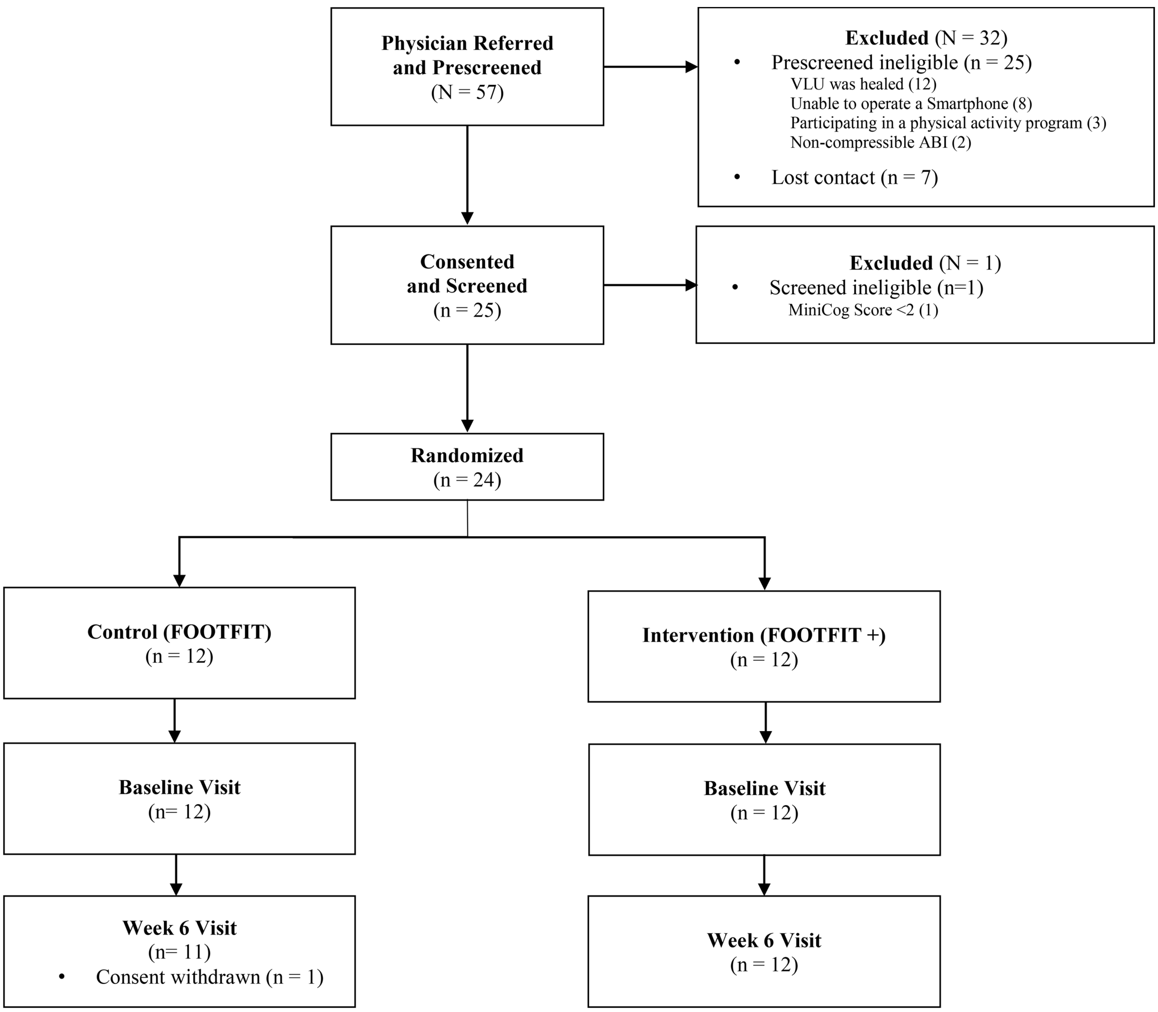

Figure. Participant CONSORT flow diagram.

TABLE 1.
Demographic and Clinical Features by Intervention Group (FOOTFIT vs FOOTFIT+) at Baseline[a]

Characteristics	FOOTFIT (n = 12)	FOOTFIT+ (n = 12)
Demographic		
Age, y	60.7 ± 13.7	69.1 ± 11.5
Sex: female	66.7% (8/12)	50.0% (6/12)
Race		
Black/African American	33.3% (4/12)	50.0% (6/12)
White	66.7% (8/12)	50.0% (6/12)
Hispanic/Latino	0% (0/12)	0% (0/12)
Educational level		
Eighth grade or less	0	8.3% (1/12)
Some high school	16.7% (2/12)	8.3% (1/12)
High school graduate	16.7% (2/12)	25.0% (3/12)
Some college	41.7% (5/12)	16.7% (2/12)
College graduate	16.7% (2/12)	41.7% (5/12)
Postgraduate and/or higher-level degree	8.3% (1/12)	0
Employment		
Employed fulltime	8.3% (1/12)	16.7% (2/12)
Not employed	41.7% (5/12)	8.3% (1/12)
Retired	50.0% (6/12)	75.0% (9/12)
Job classification		
Professional	33.3% (4/12)	41.7% (5/12)
Technical	8.3% (1/12)	16.7% (2/12)
Manual	58.3% (7/12)	41.7% (5/12)
Marital status		
Never married	16.7% (2/12)	25.0% (3/12)
Married	58.3% (7/12)	25.0% (3/12)
Separated	0	16.7% (2/12)
Divorced	16.7% (2/12)	8.3% (1/12)
Widowed	8.3% (1/12)	25.0% (3/12)
Residence		
Urban	41.7% (5/12)	75.0% (9/12)
Rural	58.3% (7/12)	25.0% (3/12)
Clinical		
Weight, lb	292.5 ± 104.0	235.0 ± 58.9
Body mass index	45.2 ± 14.5	35.5 ± 8.8
Number of ulcers	7.2 ± 4.9	5.2 ± 9.8
Age of ulcer, d	1050.7 ± 1101.4	813.8 ± 928.8
Age of ulcer, mo	35.0 ± 36.7	27.1 ± 31.0
Recurrent VLU (yes)	83.3% (10/12)	58.3% (5/12)
VLU location		
Proximal	8.3% (1/12)	8.3% (1/12)
Distal	33.3% (4/12)	33.3% (4/12)
Medial	50.0% (6/12)	25.0% (3/12)
Lateral	75.0% (9/12)	66.7% (8/12)
Anterior	33.3% (4/12)	16.7% (2/12)
Posterior	0	16.7% (2/12)

(*continues*)

TABLE 1.
Demographic and Clinical Features by Intervention Group (FOOTFIT vs FOOTFIT+) at Baseline[a]

Characteristics	FOOTFIT (n = 12)	FOOTFIT+ (n = 12)
Medications (top 5)		
Antihypertensive medicines	75.0% (9/12)	50.0% (6/12)
Cholesterol	50.0% (6/12)	50.0% (6/12)
Pain pills	58.3% (7/12(	25.0% (3/12)
Diabetes pills	33.3% (4/12)	41.7% (5/12)
Diuretics	33.3% (4/12)	33.3% (4/12)
Comorbid conditions (top 6)		
Hypertension	75.0% (9/12)	58.3% (7/12)
Arthritis	66.7% (8/12)	50.0% (6/12)
Diabetes	33.3% (4/12)	50.0% (6/12)
Thyroid problems	50.0% (6/12)	16.7% (2/12)
Varicose veins	16.7% (2/12)	33.3% (4/12)
Vein stripping	33.3% (4/12)	16.7% (2/12)

Abbreviation: VLU, venous leg ulcer.
[a]Mean ± standard deviation or percent (n/N).

their age at baseline. We found no clinically relevant changes for FOOTFIT (slight decrease −2.9 ± 5.6) and FOOTFIT+ (slight increase 3.0 ± 6.6) during the 6-week study period. For MCS, baseline and end of study scores for both groups were higher than the mean score of 50 reported in the literature; however, there were no clinically relevant changes from baseline in either group (4.2 ± 4.6 FOOTFIT; 1.1 ± 6.6 FOOTFIT+).

DISCUSSION

In this feasibility study, we randomly allocated a small group of minimally ambulatory patients with VLUs to our mHealth exercise interventions (FOOTFIT or FOOTFIT+) to gather preliminary estimates of variability on lower leg functional outcomes. The 6-week intervention period was intended to serve as an initial short exercise “boost” during wound healing treatment to slowly and gently condition the lower extremity muscles, targeting ankle flexion and strength, and determine whether even minimal gains in walking could be achieved. The intervention emphasized a self-management approach to physical exercise enabling the app user to take responsibility for how often he or she engages in an activity to improve well-being, and how intense the level of activity. As anticipated, due to the short duration of this study, we found minimal changes in clinical outcomes.

We previously conducted 2 small pilot studies of physical activity that informed this study and results showed several similarities in functional outcomes to our current study findings. The first study was a home-based online physical activity intervention developed by our team of physical therapists and exercise specialists that included CALF plus the use of resistance bands, nonexertive foot movements, and a foot peddler (similar to peddling a bicycle), delivered by a coach (a nursing student with a degree in exercise science) through online face-to-face Skype Internet sessions.[14] Five participants with lower extremity venous disease (LEVD) and a history of VLUs participated in determining the feasibility of engaging in 3 daily doses of nonexertive CALF for 1 week. We observed

TABLE 2.
Differences—Mean ± SD (Median; Range)—in Range of Motion, Strength, Mobility, and Distance Measures Between and Within Groups With 95% Confidence Intervals for Difference in Medians

Outcome	FOOTFIT	FOOTFIT+	Difference in Medians[a]	95% CI
Range of motion GON dorsiflexion right ankle				
Baseline	10.8 ± 9.4 (8.0; 1-30)	13.1 ± 6.4 (11.0; 6-25)	−1.0 (5.7)	−12.8; 10.8
wk 6	15.5 ± 11.1 (20.0; 2-40)	14.7 ± 9.0 (11.5; 6-37)	8 (4.5)	−1.4; 17.4
Change from baseline (n = 11; 12)	10.0 (5.6)	0 (4.6)	1 (2.5)	−3.1; 7.19
95% CI	−21.7; 1.7	−9.5; 9.5		...
Range of motion GON plantar flexion right ankle				
Baseline	20.9 ± 13.6 (15.0; 2-45)	24.2 ± 9.2 (22.0; 10-45)	3.0 (5.3)	−7.9; 13.9
wk 6	23.3 ± 12.8 (26.0; 2-40)	21.4 ± 10.7 (20.0; 4-45)	6 (7.8)	10.2; 22.2
Change from baseline (n = 11; 12)	−1.0 (8.5)	2.0 (4.0)	0 (3.5)	−7.2; 7.2
95% CI	−18.7; 16.7	−6.3; 10.3		...
Range of motion GON dorsiflexion left ankle				
Baseline	12.8 ± 10.7 (20.0; 1-26)	12.6 ± 9.0 (9; 2-28)	11 (7.1)	−3.8; 25.8
wk 6	19.3 ± 13.1 (20.0; 4-40)	12.8 ± 8.7 (12.0; 1-26)	8 (8.1)	−8.7; 24.7
Change from baseline (n = 10; 11)	0 (9.2)	−3.0 (6.2)	2.0 (2.7)	−3.6; 7.6
95% CI	−19.1; 19.1	−15.9; 9.9		...
Range of motion GON plantar flexion left ankle				
Baseline	22.8 ± 9.9 (21.0; 10-43)	24.7 ± 13.1 (16.0; 12-46)	4.0 (6.3)	−9.1; 17.1
wk 6	23.9 ± 9.8 (25.5; 10-42)	24.8 ± 12.1 (27.0; 10-42)	1.0 (7.5)	−14.6; 16.6
Change from baseline (n = 10; 11)	−3.0 (5.0)	−11.0 (8.2)	1.0 (1.9)	−2.9; 4.9
95% CI	−13.3; 7.3	−28.0; 6.0		...
Range of motion GON eversion right ankle				
Baseline	13.5 ± 11.6 (10.0; 3-35)	10.8 ± 8.0 (10.0; 2-30)	1.0 (8.1)	−15.7; 17.7
wk 6	11.6 ± 8.8 (10.0; 3-30)	11.3 ± 7.0 (12.0; 2-23)	−2.0 (4.2)	−10.7; 6.7
Change from baseline (n = 11; 12)	1.0 (8.3)	−2.0 (3.8)	−1.0 (1.3)	−3.8; 1.8
95% CI	−16.1; 18.1	−9.8; 5.8		...
Range of motion GON inversion right ankle				
Baseline	15.1 ± 12.9 (12.5; 0-42)	15.8 ± 6.9 (13.5; 9-30)	2.0 (5.9)	−10.2; 14.2
wk 6	14.5 ± 11.3 (12.0; 0-35)	14.2 ± 4.6 (12.0; 11-25)	0.3 ± 8.5 0 (5.5)	−11.5; 11.5
Change from baseline (n = 11; 12)	3.0 (7.1)	1.0 (3.8)	0 (1.1	−2.3; 2.3
95% CI	−11.8; 17.8	−6.8; 8.8		
Range of motion GON eversion left ankle				
Baseline	14.1 ± 11.0 (14.0; 0-35)	10.9 ± 5.8 (10.0; 3-20)	4.0 (5.3)	−7.0; 15.0
wk 6	12.2 ± 7.7 (14.0; 0-25)	10.1 ± 4.1 (9.0; 5-17)	4.0 (3.5)	−3.3; 11.3
Change from baseline (n = 10; 11)	1.0 (6.6)	1.0 (2.7)	−1.0 (1.1)	−3.3; 1.3
95% CI	−12.6; 14.6	−4.5; 6.5		...
Range of motion GON inversion left ankle				
Baseline	14.3 ± 8.9 (12.5; 3-26)	15.1 ± 6.4 (15.0; 4-25)	0 (5.3)	−10.9; 10.9
wk 6	15.8 ± 12.3 (12.0; 1-40)	16.6 ± 8.0 (17.0; 2-28)	−4.0 (7.2)	−19.0; 11.0
Change from baseline (n = 10; 11)	2.0 (6.7)	−2.0 (4.5)	0 (4.3)	−9.0; 9.0
95% CI	−12.0; 16.0	−11.3; 7.3		...
Strength DYN lb/in² dorsiflexion right ankle				
Baseline	13.0 ± 6.1 (12.0; 6-24)	14.4 ± 5.6 (12.5; 8-29)	0 (3.4)	7.1; 7.1
wk 6	18.2 ± 7.9 (17.0; 5-30)	13.2 ± 4.0 (13.0; 8-23)	4.0 (3.7)	−3.7; 11.7
Change from baseline (n = 11; 12)	5.0 (4.7)	0 (1.9)	2.0 (1.9)	−1.9; 5.9
95% CI	−14.8; 4.8	−3.9; 3.9		...

(continues)

TABLE 2.
Differences—Mean ± SD (Median; Range)—in Range of Motion, Strength, Mobility, and Distance Measures Between and Within Groups With 95% Confidence Intervals for Difference in Medians (*Continued*)

Outcome	FOOTFIT	FOOTFIT+	Difference in Medians[a]	95% CI
Strength DYN lb/in² plantar flexion right ankle				
Baseline	12.3 ± 4.7 (10.0; 6-20)	16.2 ± 12.8 (11.0; 8-51)	3.0 (3.9)	−5.0; 11.0
wk 6	13.8 ± 5.1 (15.0; 5-20)	13.3 ± 6.6 (11.5; 8-29)	3.0 (2.6)	−2.4; 8.4
Change from baseline (n = 11; 12)	−1.0 (3.2)	0 (3.4)	0 (2.1)	−4.4; 4.4
95% CI	−7.6; 5.6	−7.1; 7.1		...
Strength DYN lb/in² dorsiflexion left ankle				
Baseline	14.6 ± 8.17 (11.0; 5-27)	15.2 ± 4.5 (14.0; 10-25)	−2.0 (3.3)	−8.8; 4.8
wk 6	19.1 ± 8.8 (18.0; 3-35)	14.4 ± 4.4 (14.0; 8-23)	4.0 (3.6)	−3.5; 11.5
Change from baseline (n = 10; 11)	−6.0 (4.4)	0 (2.2)	1.0 (2.6)	−4.4; 6.4
95% CI	−15.1; 3.1	−4.5; 4.5		...
Strength DYN lb/in² plantar flexion left ankle				
Baseline	13.6 ± 5.5 (13.5; 8-25)	15.2 ± 9.3 (12.0; 6-31)	2.0 (5.0)	−8.3; 12.3
wk 6	13.7 ± 6.4 (15.5; 4-22)	13.5 ± 9.3 (10.0; 7-32)	5.0 (2.7)	−0.6; 10.6
Change from baseline (n = 10; 11)	−1.0 (4.2)	2.0 (4.3)	2.0 (1.8)	−1.6; 5.6
95% CI	−9.8; 7.8	−6.9; 10.9		
Foot and Ankle Mobility Measure score				
Baseline	49.4 ± 31.0 (39.0; 0-88)	57.9 ± 29.2 (60.0; 5-100)	4. (18.6)	−34.6; 42.6
wk 6	50.4 ± 27.9 (52.0; 0-87)	58.2 ± 31.5 (57.5; 5-98)	0 (17.1)	−35.4; 35.4
Change from baseline (n = 11; 12)	8.0 (17.8)	4.0 (17.9)	−2.0 (5.9)	−14.3; 10.3
95% CI	−29.0; 45.0	−33.1; 41.1		
6-min walking distance, ft				
Baseline	600 ± 594 (300; 0-1288)	527 ± 512 (400; 0-1375)	0 (335)	−695; 695
wk 6	608 ± 612 (300; 0-1355)	517 ± 535 (300; 0-1440)	0 (379)	−785; 785
Change from baseline (n = 9; 9)	100 (444)	100 (381)	0 (52)	−109; 109
95% CI	−821; 1021	−690; 890		

Abbreviations: CI, confidence interval; DYN, dynamometer; GON, goniometer.
[a]Difference in medians (standard error) and 95% CI obtained using quantile regression.

a high level of patient satisfaction when working with the coach and using the equipment to engage in a variety of lower leg exercises. While the goal was to test the feasibility, across the study sample ankle dorsiflexion and leg strength showed statistically significant improvements (both P values = .03). We concluded that CALF was feasible and showed promise in improving lower leg physical function. We further refined CALF in our second study of 21 minimally ambulatory patients randomized to the 6-week intervention or an exercise handout.[15] Enhancements made to CALF included the addition of a behavioral component—motivational communication delivered by certified wound care nurses to patients receiving wound care in a specialty clinic. We included only CALF (ie, we did not use the peddler or resistance bands) because participants had leg ulcers and their lower legs were wrapped with multilayer compression, restricting movement. The CALF intervention was found to be feasible and acceptable by both patients and the nurses who delivered it. Signals of improvement were noted in leg function, and pain (both P values = .04) in the lower legs of 12 patients who completed CALF compared to 9 who received the handout only. These small gains showed promise for individuals with physically deconditioned legs, especially with respect to the ability to dorsiflex the foot. Dorsiflexing the foot is an important physical function needed to effectively pump the calf muscle to eject blood out of the venous circulation, and prevents venous stasis and edema.[28,29]

We found no changes in strength, FAAM scores, or walking ability. Again, due to the short nature of the study and the original intent was user and implementation feasibility, we did not expect to find significant differences over 6 weeks. Twelve-week exercise/physical activity programs have been shown to improve many functional outcomes in addition to improved wound healing in patients with VLUs. Specifically, O'Brien and colleagues[8] demonstrated their progressive resistance exercise protocol was feasible for individuals with VLUs and those who adhered to the protocol at least 75% of the time had greater improvements in activity, functional gait and balance, range of ankle motion, and percent ulcers healed.[10,30] A longer study period with a larger sample size in our study may have corroborated findings reported in the literature. However, our intent was to promote small movements during wound treatment in patients who were sedentary, offer the intervention through an mHealth app, and while not directly measured, promote self-management.

We included measures of depression and mental health to determine whether outcomes could be explained by these psychosocial factors; however, none of the participants in our study screened positive at baseline or at study completion.

TABLE 3.
Differences—Mean ± SD (Median; Range)—in Ankle and Calf Circumference Between and Within Groups With 95% Confidence Intervals for Difference in Medians

Outcome	FOOTFIT	FOOTFIT+	Difference in Medians[a]	95% CI
Ankle circumference right foot, cm[3]				
Baseline	28.6 ± 4.7 (29.0; 20-35)	25.9 ± 4.3 (25.0; 19.5-35)	3.0 (2.6)	−2.5; 8.5
wk 6	29.0 ± 5.8 (26.2; 20-38)	25.6 ± 4.5 (24.5; 20-36.5)	1.5 (3.6)	−5.9; 8.9
Change from baseline (n = 11; 12)	2.0 (3.9)	0.5 (2.2)	0 (1.5)	−3.0; 3.0
95% CI	−6.0; 10.0	−4.1; 5.1		
Calf circumference right leg, cm				
Baseline	45.1 ± 9.6 (45.0; 31.5-61)	40.0 ± 4.8 (39.8; 32.5-47)	4.0 (4.6)	−5.6; 13.6
wk 6	46.1 ± 9.1 (46.5; 31-64.5)	40.7 ± 5.9 (40.4; 32-51)	2.2 (5.3)	−8.9; 13.3
Change from baseline (n = 11; 12)	1.5 (6.4)	1.5 (3.1)	0.5 (1.4)	−2.4; 3.4
95% CI	−11.7; 14.7	−4.9; 7.9		
Ankle circumference right foot, cm				
Baseline	29.3 ± 4.5 (28.0; 23-38)	25.5 ± 3.2 (26.0; 20-30.5)	2.0 (1.9)	−1.9; 5.9
wk 6	26.0 ± 8.6 (27.8; 9.5-35)	25.61 ± 3.0 (24.5; 20.5-30)	3.0 (3.5)	−4.2; 10.2
Change from baseline (n = 10; 11)	0 (3.4)	1.5 (2.0)	0.5 (1.1)	−1.8; 2.8
95% CI	−7.1; 7.1	−2.6; 5.6		
Calf circumference left leg, cm				
Baseline	44.9 ± 8.1 (43.5; 33-59)	40.7 ± 5.0 (41.5; 32-48.5)	3.5 (3.9)	−4.6; 11.6
wk 6	39.3 ± 13.7 (43.8; 15.5-58)	41.8 ± 6.3 (41.0; 32-51)	1.0 (6.4)	−12.2; 14.2
Change from baseline (n = 10; 11)	3.0 (6.9)	0.5 (3.6)	0 (2.5)	−5.2; 5.2
95% CI	−11.3; 17.3	−7.0; 8.0		

Abbreviation: CI, confidence interval.
[a]Difference in medians (standard error) and 95% CI obtained using quantile regression.

Mental health findings are inconsistent among studies of patients with VLUs; 50% of patients with VLUs were found to report depression measured with the GDS in one study[31] compared to 22.2% in another study, in which depression was measured with the Hospital Anxiety and Depression Scale.[32] In the latter study, the mental health component of the SF-12 MCS score of 48.2 was lower than our MCS score of 58.2, both of which were close to the mean score of 50 reported in the

TABLE 4.
Differences—Mean ± SD (Median; Range)—in Depression and Quality of Life Between and Within Groups With 95% Confidence Intervals for Difference in Medians

Outcome	FOOTFIT	FOOTFIT+	Difference in Medians[a]	95% CI
Geriatric Depression Scale total score				
Baseline	3.4 ± 3.6 (2.0; 0-11)	1.8 ± 1.9 (1.0; 0-6)	1.0 (1.7)	−2.6; 4.6
wk 6	2.8 ± 3.0 (2.0; 0-10)	1.6 ± 2.2 (0.5; 0-7)	1.0 (1.2)	−1.6; 3.6
Change from baseline (n = 11; 12)	1.0 (1.8)	0 (1.2)	1.0 (1.0)	−1.2; 3.2
95% CI	−2.6; 4.6	−2.5; 2.5	...	...
SF-12 physical component score				
Baseline	30.2 ± 10.6 (28.9; 17.7-49.6)	36.0 ± 10.6 (36.2; 22.1-50.0)	−1.9 (7.6)	−17.7; 13.9
wk 6	27.3 ± 9.6 (23.9; 16.6-42.4)	39.0 ± 9.9 (37.6; 23.3-56.2)	−4.4 (6.0)	−16.9; 8.1
Change from baseline (n = 8; 12)	4.9 (7.8)	1.5 (6.5)	4.5 (3.1)	−11.0; 2.0
95% CI	−11.3; 21.1	−12.1; 15.1	...	...
SF-12 mental component score				
Baseline	53.7 ± 5.9 (54.1; 45.8-60.8)	60.2 ± 5.7 (60.8; 49.5-68.5)	−4.7 (4.2)	−13.3; 3.9
wk 6	57.9 ± 7.4 (61.2; 45.1-64.5)	61.3 ± 4.8 (61.6; 50.7-67.7)	0.9 (2.5)	−4.2; 6.0
Change from baseline (n = 8; 12)	−5.0 (5.2)	0.6 (3.0)	3.0 (3.0)	−3.3; 9.3
95% CI	−15.8; 5.8	−5.5; 6.7	...	...

Abbreviation: CI, confidence interval; SF-12, 12-Item Short-Form Health Survey.
[a]Difference in medians (standard error) and 95% CI obtained using quantile regression.

literature, and indicated average mental health functioning.[32] Thus, mental health was considered to be good despite this sample's physical challenges and do not negatively influence study outcomes. The physical health component PCS score of 33.1 found in our study was similar to the later study PCS score of 35.9 suggesting below average physical functioning.[32] Poor foot function and strength and lower physical functioning are negatively associated with slower wound healing; however, whether mental health adversely affects healing remains inconclusive.

Strengths and Limitations

Our study contributes preliminary information on functional outcomes of a foot-based accelerometer (BEAT) designed for a minimally ambulatory population with VLUs and an mHealth app to promote evidence-based lower extremity conditioning exercises (CALF) through a 6-week progressive, self-managed intervention. The main strength of this study aim relates to the innovative nature of delivering an exercise intervention to enhance self-managed physical activity in which participants need not leave their homes. There are some limitations to our study. Our primary aim was to explore feasibility of the FOOTFIT interventions; thus, the number of participants was small and findings should be considered exploratory. We did not target healing as an outcome owing to the relatively brief (6-week) participation time frame. In addition, individuals were enrolled at any point during their wound treatment; thus, we could not control healing trajectories, or types of wound treatment used.

CONCLUSIONS

Lower leg exercise, a component of physical activity, improves calf muscle pump function and range of motion in individuals with LEVD and VLUs. Nevertheless, in our minimally ambulatory population, we observed that the mHealth FOOTFIT app, used over a brief period of 6 weeks, demonstrated minimal efficacy. Future studies should consider the use of patient-reported outcome measures and other self-report-type questionnaires about engagement in and experiences with exercise interventions. Finally, as evidence supporting simple progressive resistance and prescribing physical activity suitable to individuals with VLUs continues to evolve, innovative methods that assist individuals with VLUs to self-manage these activities should be the target of further research to enhance uptake and adherence. The goal is to provide a more "holistic" management plan for individuals with VLUs.

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