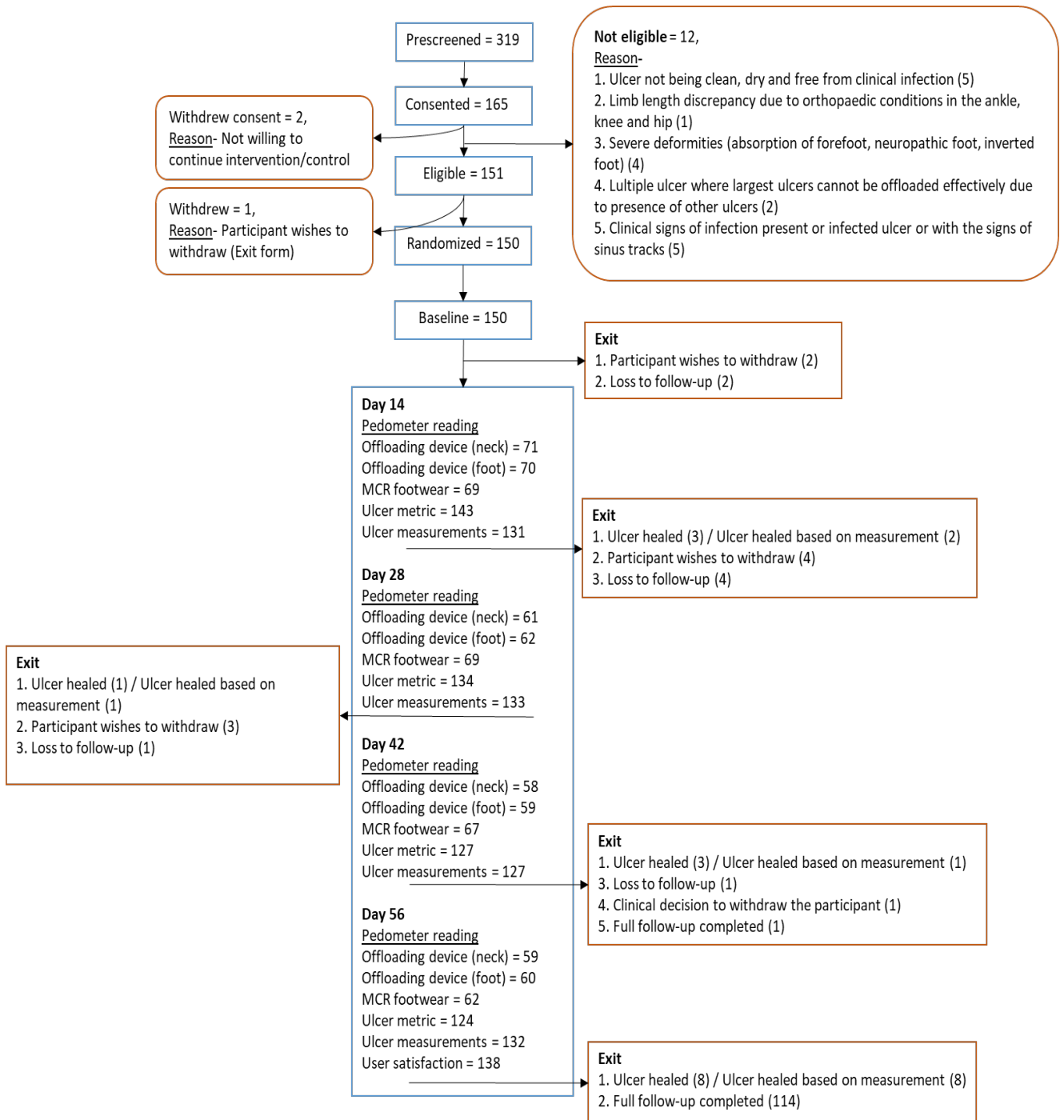


Leprosy offloading v/s MRC footwear

2025-05-19



A total of 319 participants were pre-screened, and 150 participants were randomized into the study.

Follow-up assessments were conducted at days 14, 28, 42, and 56, By day 56, 114 participants completed the full follow-up, with 8 ulcers healed during this period (Fig 2).

Table 1

Table 1. Baseline characteristics		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Age (in years)		
N	76.00	74.00
Mean (SD)	51.68 (12.64)	53.95 (13.29)
Median (IQR)	52.50 (44.50, 60.00)	55.00 (45.00, 62.00)
Min Max	24.00 95.00	24.00 88.00
Gender, n / N (%)		
1. Female	24 / 76 (31.58%)	23 / 74 (31.08%)
2. Male	52 / 76 (68.42%)	51 / 74 (68.92%)
Marital status, n / N (%)		
1. Single	6 / 76 (7.89%)	4 / 74 (5.41%)
2. Married	59 / 76 (77.63%)	60 / 74 (81.08%)
3. Divorced	1 / 76 (1.32%)	2 / 74 (2.70%)
4. Widowed	10 / 76 (13.16%)	8 / 74 (10.81%)
Height (in cms)		
N	76.00	74.00
Mean (SD)	159.04 (9.38)	158.92 (8.68)
Median (IQR)	156.50 (152.50, 165.00)	159.00 (153.00, 164.00)

Table 1. Baseline characteristics

Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Min Max	144.00 193.00	132.00 192.00
Weight (in kg)		
N	76.00	74.00
Mean (SD)	55.89 (11.32)	56.07 (9.34)
Median (IQR)	55.00 (47.00, 64.00)	57.00 (48.00, 63.00)
Min Max	36.00 87.00	31.00 75.00
BMI (in kg/m²)		
N	76.00	74.00
Mean (SD)	22.05 (3.76)	22.22 (3.45)
Median (IQR)	21.18 (19.24, 24.61)	22.55 (19.07, 24.78)
Min Max	13.41 29.90	13.56 29.33
Employment, n / N (%)		
1. Farming	14 / 76 (18.42%)	25 / 74 (33.78%)
2. Job	5 / 76 (6.58%)	6 / 74 (8.11%)
3. Self-employed/Own business	8 / 76 (10.53%)	9 / 74 (12.16%)
4. Labourer	19 / 76 (25.00%)	6 / 74 (8.11%)
5. Student	0 / 76 (0.00%)	0 / 74 (0.00%)
6. House wife	6 / 76 (7.89%)	11 / 74 (14.86%)

Table 1. Baseline characteristics

Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
7. Unemployed	17 / 76 (22.37%)	11 / 74 (14.86%)
8. Unable to work due to disability	7 / 76 (9.21%)	6 / 74 (8.11%)
Family income per month, n / N (%)		
1. <10,000	42 / 76 (55.26%)	40 / 74 (54.05%)
2. 10,001 - 20,000	23 / 76 (30.26%)	17 / 74 (22.97%)
3. 20,001 - 30,000	6 / 76 (7.89%)	7 / 74 (9.46%)
4. 30,001 - 50,000	2 / 76 (2.63%)	3 / 74 (4.05%)
5. 50,001 - 80,000	2 / 76 (2.63%)	4 / 74 (5.41%)
6. 80,001 - 100,000	0 / 76 (0.00%)	1 / 74 (1.35%)
7. Above 100,000	1 / 76 (1.32%)	2 / 74 (2.70%)
Smokeless tobacco, n / N (%)		
1. Past user	5 / 76 (6.58%)	3 / 74 (4.05%)
2. Current user	18 / 76 (23.68%)	21 / 74 (28.38%)
3. Never used	53 / 76 (69.74%)	50 / 74 (67.57%)
Smoking tobacco, n / N (%)		
1. Past smoker	8 / 76 (10.53%)	12 / 74 (16.22%)
2. Current smoker	10 / 76 (13.16%)	3 / 74 (4.05%)
3. Never smoked	58 / 76 (76.32%)	59 / 74 (79.73%)

Table 1. Baseline characteristics		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Daily time spent in walking (in hours)		
N	76.00	74.00
Mean (SD)	2.61 (1.42)	2.54 (1.46)
Median (IQR)	2.33 (1.71, 3.00)	2.17 (1.67, 3.00)
Min Max	0.50 8.00	0.67 10.00

Table 1 highlights the demographic, physical, and socioeconomic similarities and differences between the two groups of participants in two groups: Offloading Device (N=76) and MCR Footwear (N=74).

The mean age was 51.7 years for the Offloading Device group and 54.0 years for the MCR footwear group. Both groups had similar gender distributions, with approximately 31% female and 69% male participants. 78.% participants in Offloading Device and 81% in MCR Footwear were married. Mean height of the participants was 159.04 cm for Offloading Device and 158.92 cm for MCR Footwear. Mean BMI values were 22.1 kg/m² for Offloading Device and 22.2 kg/m² for MCR Footwear.

Farming was more common in the MCR Footwear group compared to Offloading Device. Labourers were more prevalent in the Offloading Device group (25. %). Most participants had monthly family incomes below ₹10,000 in both groups. Smokeless tobacco use was similar across groups, with most participants being non-users. Mean daily walking times were 2.6 hours for Offloading Device and 2.5 hours for MCR Footwear.

Table 2

Table 2. Baseline clinical conditions		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Sensory loss, n / N (%)		
1. Yes	74 / 76 (97.37%)	73 / 74 (98.65%)
2. No	2 / 76 (2.63%)	1 / 74 (1.35%)
Leprosy status, n / N (%)		
1. Yes	67 / 76 (88.16%)	69 / 74 (93.24%)
2. No	9 / 76 (11.84%)	5 / 74 (6.76%)
Duration of leprosy (in years)		
N	67.00	69.00
Mean (SD)	16.58 (13.82)	17.35 (15.47)
Median (IQR)	10.17 (6.42, 25.00)	12.00 (5.25, 26.00)
Min Max	0.50 65.00	0.58 60.00
(Missing)	9	5
Dorsalis pedis pulse, n / N (%)		
1. Absent	1 / 14 (7.14%)	1 / 11 (9.09%)
2. Present	11 / 14 (78.57%)	10 / 11 (90.91%)
3. Diminished	2 / 14 (14.29%)	0 / 11 (0.00%)
(Missing)	62	63
Diabetes, n / N (%)		

Table 2. Baseline clinical conditions		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
1. Yes	14 / 76 (18.42%)	11 / 74 (14.86%)
2. No	62 / 76 (81.58%)	63 / 74 (85.14%)
Type of diabetes, n / N (%)		
1. Type I	0 / 14 (0.00%)	0 / 11 (0.00%)
2. Type II	14 / 14 (100.00%)	11 / 11 (100.00%)
(Missing)	62	63
Duration of diabetes (in years)		
N	14.00	11.00
Mean (SD)	7.91 (6.04)	8.04 (6.11)
Median (IQR)	6.25 (4.25, 10.00)	7.17 (3.00, 10.00)
Min Max	0.08 20.42	1.42 20.50
(Missing)	62	63
Hypertension, n / N (%)		
1. Yes	6 / 76 (7.89%)	8 / 74 (10.81%)
2. No	70 / 76 (92.11%)	66 / 74 (89.19%)
Duration of hypertension (in years)		
N	6.00	8.00
Mean (SD)	7.40 (6.01)	4.80 (5.30)

Table 2. Baseline clinical conditions		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Median (IQR)	8.08 (0.75, 12.00)	2.63 (1.54, 7.50)
Min Max	0.50 15.00	0.08 15.00
(Missing)	70	66
Eye, Hand, and Foot score		
N	76.00	74.00
Mean (SD)	4.58 (2.46)	4.86 (2.29)
Median (IQR)	4.00 (2.00, 6.50)	4.50 (3.00, 8.00)
Min Max	2.00 10.00	2.00 9.00
Foot EHF score		
N	76.00	74.00
Mean (SD)	2.86 (0.87)	3.01 (0.88)
Median (IQR)	3.00 (2.00, 4.00)	3.00 (2.00, 4.00)
Min Max	2.00 4.00	2.00 4.00

Nearly all participants had sensory loss (97.4% in Offloading Device and 98.7% in MCR Footwear). Duration of leprosy in most participants was 16.6 years in offloading device and 17.4 years in MCR chappal, respectively. Among those assessed for presence of dorsalis pedis pulse, the pulse was present in 78.6% of Offloading Device participants and 90.9% of MCR Footwear participants. Type II diabetes was present in 18.4% of Offloading Device participants and 15.0 % of MCR Footwear participants, with mean durations of

7.9 years and 8.0 years, respectively. Hypertension was reported in 8 % of Offloading Device participants and 11% of MCR Footwear participants.

Mean Foot EHF scores were 4.6 for Offloading Device and 4.7 for MCR Footwear and the Mean Foot EHF scores were 2.7 (SD: 0.87) for Offloading Device and 3.0 (SD: 0.88) for MCR Footwear.

Table 3

Table 3. Baseline limb and ulcer details		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Duration of foot impairment (in years)		
N	76.00	74.00
Mean (SD)	12.25 (11.90)	13.26 (14.87)
Median (IQR)	6.67 (3.50, 19.00)	5.58 (2.50, 20.00)
Min Max	0.50 45.00	0.25 58.00
History of pervious amputation, n / N (%)		
1. Yes	24 / 76 (31.58%)	22 / 74 (29.73%)
2. No	52 / 76 (68.42%)	52 / 74 (70.27%)
Sub-talar joint alignment, n / N (%)		
1. Neutral	20 / 76 (26.32%)	11 / 74 (14.86%)
2. Supinated	15 / 76 (19.74%)	18 / 74 (24.32%)
3. Pronated	41 / 76 (53.95%)	45 / 74 (60.81%)
Claw toes, n / N (%)		
1. Yes	23 / 76 (30.26%)	22 / 74 (29.73%)

Table 3. Baseline limb and ulcer details		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
2. No	53 / 76 (69.74%)	52 / 74 (70.27%)
Number of ulcers, n / N (%)		
1	59 / 76 (77.63%)	59 / 74 (79.73%)
2	16 / 76 (21.05%)	15 / 74 (20.27%)
3	1 / 76 (1.32%)	0 / 74 (0.00%)
Site of index ulcer, n / N (%)		
1. Fore foot	55 / 76 (72.37%)	51 / 74 (68.92%)
2. Mid foot	15 / 76 (19.74%)	12 / 74 (16.22%)
3. Heel	6 / 76 (7.89%)	11 / 74 (14.86%)
Duration of index ulcer (in years)		
N	76.00	74.00
Mean (SD)	2.12 (2.32)	2.62 (5.99)
Median (IQR)	1.21 (0.50, 2.75)	1.13 (0.50, 2.50)
Min Max	0.08 10.00	0.08 48.00
Ulcer recurrence, n / N (%)		
1. First	27 / 76 (35.53%)	26 / 74 (35.14%)
2. Second	18 / 76 (23.68%)	22 / 74 (29.73%)
3. Third	11 / 76 (14.47%)	11 / 74 (14.86%)

Table 3. Baseline limb and ulcer details		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
4. Fourth	5 / 76 (6.58%)	7 / 74 (9.46%)
5. Fifth	1 / 76 (1.32%)	0 / 74 (0.00%)
6. More than 5 times	14 / 76 (18.42%)	8 / 74 (10.81%)

Table 3 (appendix) provides baseline details about limb and ulcer conditions for participants in the Offloading Device (N=76) and MCR Footwear (N=74) groups. Mean durations of foot impairment were 12.3 for Offloading Device and 13.3 years for MCR Footwear. 1.6% of Offloading Device participants and 29.7% of MCR Footwear participants had a history of amputation of digits. Most participants had pronated feet (54.0 % in Offloading Device and 61.0 % in MCR Footwear). Claw Toes were present in 30.3% of Offloading Device participants and 29.7% of MCR Footwear participants. Most participants had one ulcer (77.6% in Offloading Device and 79.7% in MCR Footwear) the forefoot being the most common site of the index ulcer. First ulcer recurrence was most common (35.5% in Offloading Device and 35.1% in MCR Footwear), with fewer participants experiencing multiple recurrences.

Table 4 summarizes outcomes related to ulcer healing, pedometer readings (adherence) , and user satisfaction for participants in the Offloading Device (N=76) and MCR Footwear (N=74) groups

Table 4

Table 4. Outcomes (Descriptives)- Ulcer healing,		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Ulcer healed at day 14, n / N (%)		
1. Yes	2 / 70 (2.86%)	1 / 73 (1.37%)

Table 4. Outcomes (Descriptives)- Ulcer healing,		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
2. No	68 / 70 (97.14%)	72 / 73 (98.63%)
Missing	6	1
Ulcer healed at day 28, n / N (%)		
1. Yes	1 / 63 (1.59%)	1 / 71 (1.41%)
2. No	62 / 63 (98.41%)	70 / 71 (98.59%)
Missing	13	3
Ulcer healed at day 42, n / N (%)		
1. Yes	1 / 59 (1.69%)	2 / 68 (2.94%)
2. No	58 / 59 (98.31%)	66 / 68 (97.06%)
Missing	17	6
Ulcer healed at day 56, n / N (%)		
1. Yes	7 / 60 (11.67%)	1 / 64 (1.56%)
2. No	53 / 60 (88.33%)	63 / 64 (98.44%)
Missing	16	10
Ulcer healed at day 14 (based on ulcer picture measurements), n / N (%)		
1. Yes	1 / 70 (1.43%)	1 / 73 (1.34%)
2. No	69 / 70 (98.57%)	72 / 73 (98.63%)
Missing	6	1
Ulcer healed at day 28 (based on ulcer picture measurements), n / N (%)		
1. Yes	1 / 62 (1.61%)	0 / 70 (0.00%)
2. No	61 / 62 (98.39%)	70 / 70 (100%)
Missing	14	4

Table 4. Outcomes (Descriptives)- Ulcer healing,		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Ulcer healed at day 42 (based on ulcer picture measurements), n / N (%)		
1. Yes	0 / 58 (0.00%)	1 / 67 (1.49%)
2. No	58 / 58 (100.0%)	66 / 67 (98.51%)
Missing	18	7
Ulcer healed at day 56 (based on ulcer picture measurements), n / N (%)		
1. Yes	2 / 55 (3.64%)	4 / 63 (6.35%)
2. No	53 / 55 (96.36%)	59 / 64 (93.65%)
Missing	21	11
<p>The healing rates were very low overall in both groups until day 42. By day 14 and day 28, almost no ulcers had healed in either group (<3%), implying that early complete ulcer healing is rare with either intervention. At day 56, clinical assessment showed that 7 out of 60 ulcers (11.7%) had healed in the offloading device group, compared to 1 out of 64 (1.6%) in the MCR footwear group. This could be because of a possible benefit of offloading devices for ulcer healing at this time point. At day 56, based on ulcer picture measurements, 2 out of 55 ulcers (3.6%) had healed in the offloading device group, while 4 out of 63 (6.3%) had healed in the MCR footwear group. This contrasts with the clinical assessment, showing slightly more healing in the MCR group by picture measurement.</p>		
Outcomes (Descriptives)- new ulcer		
New ulcer at day 14, n / N (%)		
1. Yes	2 / 70 (2.86%)	3 / 73 (4.11%)
2. No	68 / 70 (97.14%)	70 / 73 (95.89%)
Missing	6	1
New ulcer at day 28, n / N (%)		
1. Yes	2 / 63 (3.17%)	2 / 71 (2.82%)

Table 4. Outcomes (Descriptives)- Ulcer healing,		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
2. No	61 / 63 (96.83%)	69 / 71 (97.18%)
Missing	13	3
New ulcer at day 42, n / N (%)		
1. Yes	1 / 59 (1.69%)	0 / 68 (0.00%)
2. No	58 / 59 (98.31%)	68 / 68 (100.00%)
Missing	17	6
New ulcer at day 56, n / N (%)		
1. Yes	2 / 60 (3.33%)	1 / 64 (1.56%)
2. No	58 / 60 (96.67%)	63 / 64 (98.44%)
Missing	16	10
<p>The incidence of new ulcers was low across both groups throughout the follow-up period. At day 14, new ulcers were observed in 2 of 70 participants (2.9%) in the offloading device group and 3 of 73 (4.1%) in the MCR footwear group. At day 28, new ulcers occurred in 2 of 63 (3.2%) in the offloading device group and 2 of 71 (2.8%) in the MCR footwear group. At day 42, one new ulcer was reported in the offloading device group (1.7%), while no new ulcers were reported in the MCR footwear group. By day 56, new ulcers were noted in 2 of 60 participants (3.3%) in the offloading device group and 1 of 64 (1.6%) in the MCR footwear group. Overall, the incidence of new ulcer formation was low and comparable between the two groups, with no differences across time points.</p>		
Outcomes (Descriptives)- Pedometer readings		
Total pedometer (device) reading		
N	71.00	0.00
Mean (SD)	76,571.17 (82,974.48)	NA (NA)
Median (IQR)	50,722.00 (24,778.00, 102,631.00)	NA (NA, NA)
Min Max	562.00 488,293.00	Inf -Inf

Table 4. Outcomes (Descriptives)- Ulcer healing,

Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Missing	5	74
Total pedometer (neck) reading		
N	72.00	73.00
Mean (SD)	102,147.86 (98,637.54)	177,414.01 (175,717.96)
Median (IQR)	73,813.00 (30,968.50, 131,049.50)	111,512.00 (59,073.00, 248,156.00)
Min Max	665.00 478,108.00	4,313.00 774,168.00
Missing	4	1
Pedometer (device) reading at day 14 (0 to 14 days)		
N	70.00	0.00
Mean (SD)	17,074.46 (17,207.43)	NA (NA)
Median (IQR)	11,428.50 (5,527.00, 19,196.00)	NA (NA, NA)
Min Max	304.00 86,213.00	Inf -Inf
Missing	6	74
Pedometer (device) reading at day 28 (15 to 28 days)		
N	62.00	0.00
Mean (SD)	21,646.89 (26,799.26)	NA (NA)
Median (IQR)	12,185.00 (6,323.00, 27,040.00)	NA (NA, NA)
Min Max	375.00 150,173.00	Inf -Inf
Missing	14	74
Pedometer (device) reading at day 42 (29 to 42 days)		
N	59.00	0.00

Table 4. Outcomes (Descriptives)- Ulcer healing,

Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Mean (SD)	25,517.56 (28,983.46)	NA (NA)
Median (IQR)	15,745.00 (6,810.00, 32,972.00)	NA (NA, NA)
Min Max	176.00 164,576.00	Inf -Inf
Missing	17	74
Pedometer (device) reading at day 56 (43 to 56 days)		
N	60.00	0.00
Mean (SD)	23,228.30 (27,778.79)	NA (NA)
Median (IQR)	13,839.50 (7,525.50, 29,453.00)	NA (NA, NA)
Min Max	48.00 160,544.00	Inf -Inf
Missing	16	74
Pedometer (neck) reading at day 14 (0 to 14 days)		
N	71.00	69.00
Mean (SD)	28,685.82 (32,223.59)	44,611.64 (48,514.23)
Median (IQR)	18,436.00 (7,840.00, 34,198.00)	23,753.00 (9,967.00, 71,292.00)
Min Max	665.00 188,110.00	0.00 223,136.00
Missing	5	5
Pedometer (neck) reading at day 28 (15 to 28 days)		
N	61.00	69.00
Mean (SD)	27,787.92 (29,330.74)	48,119.33 (54,082.85)
Median (IQR)	18,926.00 (8,044.00, 37,946.00)	24,575.00 (11,888.00, 66,488.00)

Table 4. Outcomes (Descriptives)- Ulcer healing,

Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
Min Max	0.00 146,410.00	120.00 320,191.00
Missing	15	5
Pedometer (neck) reading at day 42 (29 to 42 days)		
N	58.00	67.00
Mean (SD)	31,678.74 (35,025.82)	51,019.42 (50,042.43)
Median (IQR)	20,082.00 (8,835.00, 41,716.00)	33,373.00 (12,987.00, 66,887.00)
Min Max	0.00 174,196.00	19.00 197,279.00
Missing	18	7
Pedometer (neck) reading at day 56 (43 to 56 days)		
N	59.00	62.00
Mean (SD)	30,263.10 (35,595.45)	50,556.21 (59,465.67)
Median (IQR)	17,376.00 (6,991.00, 38,394.00)	32,485.50 (11,356.00, 63,552.00)
Min Max	0.00 185,894.00	553.00 301,961.00
Missing	17	12

Neck-worn pedometers consistently recorded higher step counts in the MCR footwear group compared with the offloading device group. At day 14, mean steps were 28,685.8 (SD 32,223.6) in the offloading device group and 44,611.6 (SD 48,514.2) in the MCR group; similar differences persisted at days 28, 42, and 56.

Median values also reflected higher mobility in the MCR group.

Device-embedded pedometer readings in the offloading device group, showed step counts increased over time from a mean of 17,074.5 at day 14 to 23,228.3 at day 56, suggesting progressive adaptation to the device.

Table 4. Outcomes (Descriptives)- Ulcer healing,

Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
User satisfaction- Device score		
N	67.00	71.00
Mean (SD)	3.87 (0.85)	4.43 (0.59)
Median (IQR)	4.00 (3.25, 4.50)	4.63 (4.13, 4.88)
Min Max	1.88 5.00	2.38 .00
Missing	9	3
User satisfaction- Dimensions (size, height, length, width)		
N	67.00	71.00
Mean (SD)	3.84 (0.86)	4.38 (0.98)
Median (IQR)	4.00 (3.00, 5.00)	5.00 (4.00, 5.00)
Min Max	2.00 5.00	1.00 5.00
Missing	9	3
User satisfaction- Weight		
N	67.00	71.00
Mean (SD)	3.81 (1.03)	4.42 (0.84)
Median (IQR)	4.00 (3.00, 5.00)	5.00 (4.00, 5.00)
Min Max	2.00 5.00	1.00 5.00
Missing	9	3
User satisfaction- Ease of adjustment (fixing, fastening)		
N	67.00	71.00
Mean (SD)	3.85 (1.02)	4.55 (0.77)
Median (IQR)	4.00 (3.00, 5.00)	5.00 (4.00, 5.00)
Min Max	1.00 5.00	2.00 5.00
Missing	9	3

Table 4. Outcomes (Descriptives)- Ulcer healing,		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
User satisfaction- Safety and security		
N	67.00	71.00
Mean (SD)	3.82 (1.19)	4.56 (0.75)
Median (IQR)	4.00 (3.00, 5.00)	5.00 (4.00, 5.00)
Min Max	1.00 5.00	2.00 5.00
Missing	9	3
User satisfaction- Durability (endurance, resistance to wear)		
N	67.00	71.00
Mean (SD)	4.19 (0.93)	4.23 (0.83)
Median (IQR)	4.00 (3.00, 5.00)	4.00 (4.00, 5.00)
Min Max	2.00 5.00	2.00 5.00
Missing	9	3
User satisfaction- Ease to use		
N	67.00	71.00
Mean (SD)	3.78 (1.03)	4.63 (0.70)
Median (IQR)	4.00 (3.00, 5.00)	5.00 (4.00, 5.00)
Min Max	1.00 5.00	1.00 5.00
Missing	9	3
User satisfaction- Comfort		
N	67.00	71.00
Mean (SD)	3.78 (1.15)	4.62 (0.66)
Median (IQR)	4.00 (3.00, 5.00)	5.00 (4.00, 5.00)
Min Max	1.00 5.00	3.00 5.00
Missing	9	3
User satisfaction- Effectiveness		

Table 4. Outcomes (Descriptives)- Ulcer healing,

Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74
N	67.00	71.00
Mean (SD)	3.88 (1.14)	4.01 (1.10)
Median (IQR)	4.00 (3.00, 5.00)	4.00 (3.00, 5.00)
Min Max	1.00 5.00	1.00 5.00
Missing	9	3

Overall device satisfaction scores were higher in the MCR footwear group compared with the offloading device group (mean 4.43 ± 0.59 vs. 3.87 ± 0.85 , respectively).

For dimensions (size, height, length, width), MCR footwear was rated more favourably (mean 4.38 ± 0.98 vs. 3.84 ± 0.86). Similarly, satisfaction with weight was higher in the MCR group (4.42 ± 0.84 vs. 3.81 ± 1.03).

Ease of adjustment (fixing, fastening) and perceptions of safety/security were also better rated in the MCR footwear group (mean 4.55 ± 0.77 and 4.56 ± 0.75 , respectively) compared with the offloading device group (3.85 ± 1.02 and 3.82 ± 1.19).

Satisfaction regarding durability was similar across groups (MCR: 4.23 ± 0.83 ; device: 4.19 ± 0.93). However, MCR footwear was considered better than the offloading device in domains of ease of use (4.63 ± 0.70 vs. 3.78 ± 1.03) and comfort (4.62 ± 0.66 vs. 3.78 ± 1.15).

However, rates of perceived effectiveness were comparable between groups (device: 3.88 ± 1.14 ; MCR footwear: 4.01 ± 1.10).

Taken together, these findings indicate that while the offloading device may provide some clinical benefit in ulcer healing, patients found MCR footwear more acceptable, easier to use, and more comfortable across most satisfaction domains. This difference in acceptability could have important implications for long-term adherence and effectiveness.

Table 4. Outcomes (Descriptives)- Ulcer healing,		
Characteristic	Group	
	Offloading device N = 76	MCR footwear N = 74

Fig. 1 Weekly pedometer reading in intervention arm

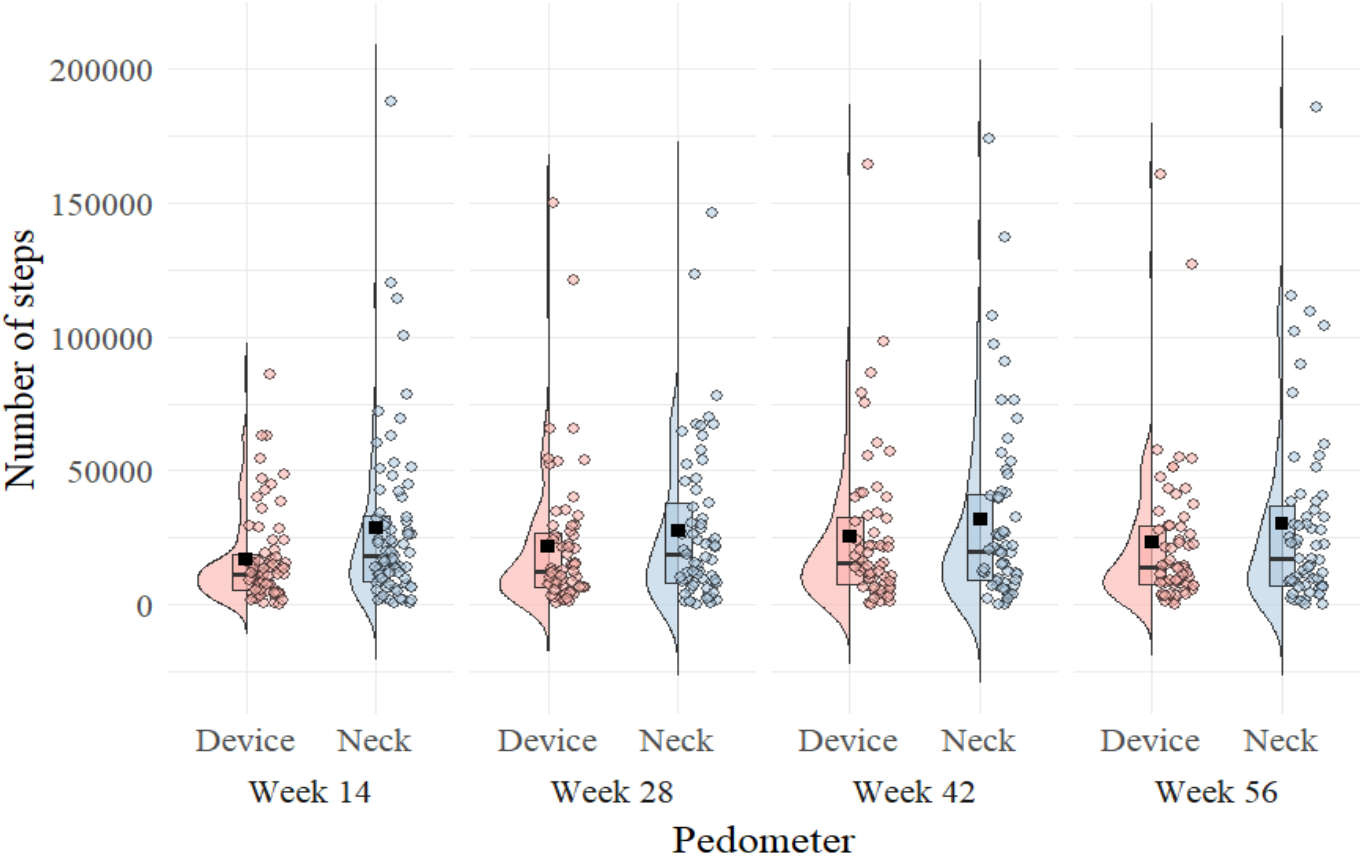


Fig. 2 User satisfaction

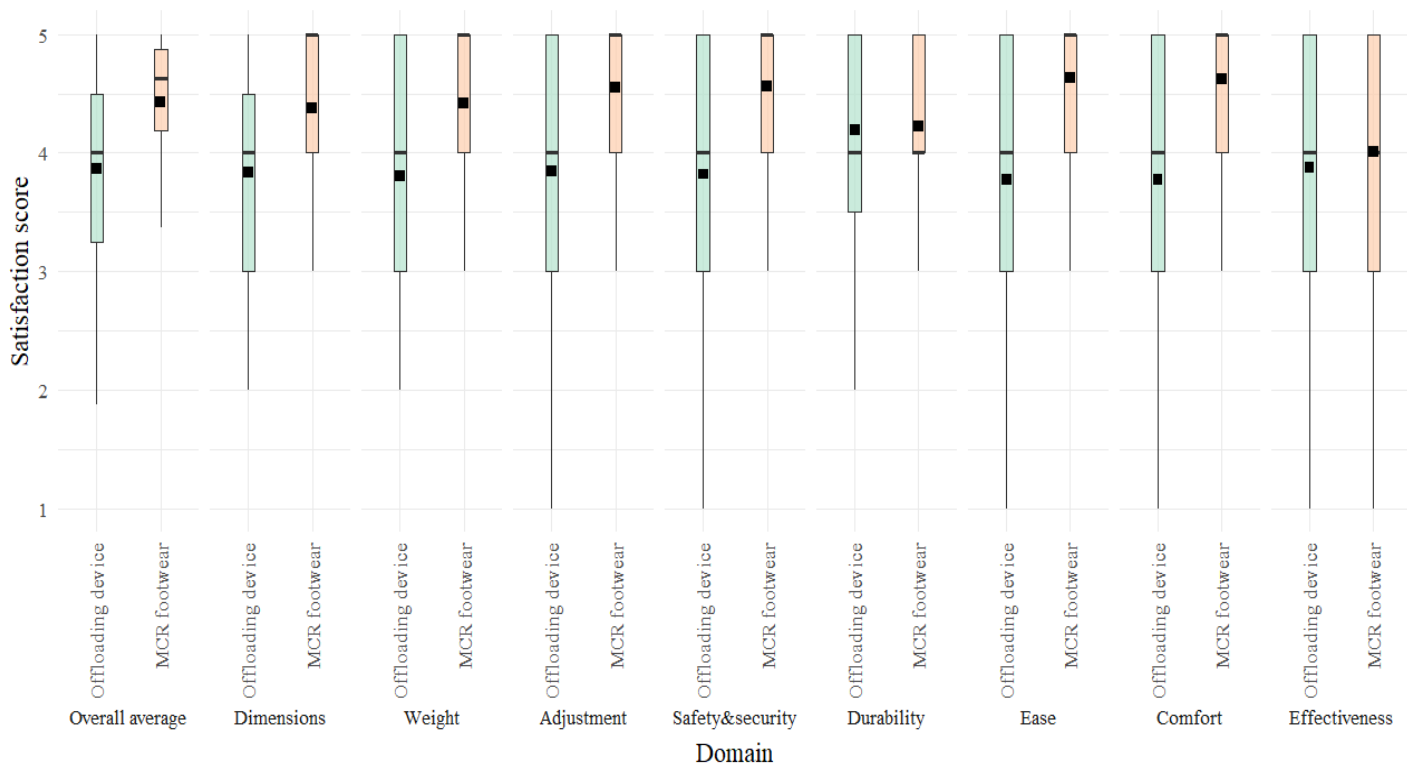


Table. Incidence rate ratio of new ulcer

Table. Ratio of incidence rates (per 100 person days) of new ulcer between MCR footwear and Offloading device

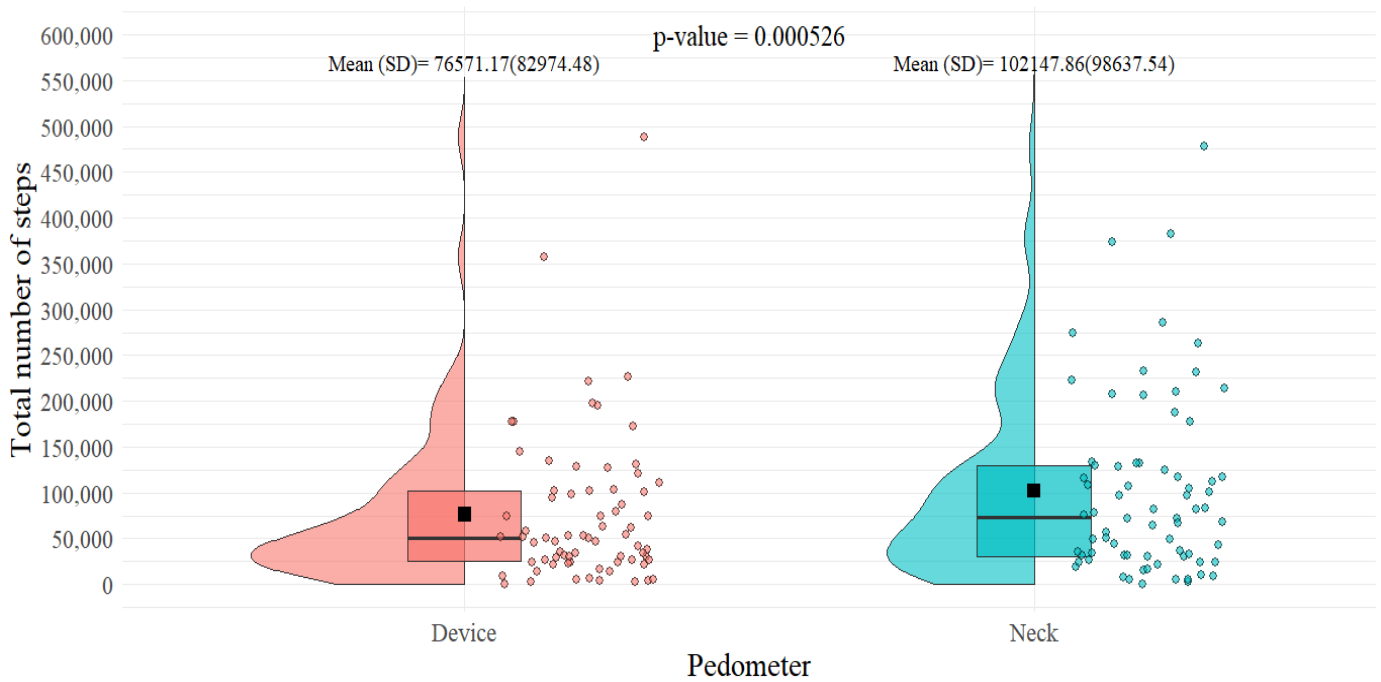
MCR footwear [Rate per year (SE)]	Offloading device [Rate per year (SE)]	Unadjusted-Rate ratio [95% CI]	p-value
0.49(0.22)	0.73(0.27)	1.47(0.47,4.64)	0.509

The incidence of new ulcers was 0.49 per person-year among those using MCR sandals and 0.73 per person-year among those using the offloading device. This means approximately one new ulcer every two years with MCR footwear, compared to about 3 new ulcers every 4 years or 1 new ulcer every 1.37 years for a person using the offloading device. Although the offloading device group showed a higher rate of new ulcer occurrence (rate ratio 1.47, 95% CI 0.47–4.64), this difference was not statistically significant ($p = 0.509$). Thus, MCR sandals performed comparably to the more specialized offloading device in preventing new ulcers.

Table 5

Table 5. Adherence with offloading device (N=76)				
Neck [Mean (SD)]	Foot [Mean (SD)]	Mean difference [95% CI]	t-statistics	p-value
102147.86 (98637.54)	76571.17 (82974.48)	25997.46 (11734.14; 40260.79)	3.64	0.00053
<i>Note:</i> Difference between number of steps in neck and foot pedometer reading (offloading device)				
<p>Adherence to the prescribed use of the offloading device was assessed by comparing pedometer readings worn on the foot (reflecting actual device use) and on the neck (reflecting overall physical activity).</p> <p>The mean step count recorded by the foot pedometer was 76,571.17 (SD 82,974.48), which was significantly lower than the neck pedometer readings. The mean difference between neck and foot pedometer counts was 25,997.46 steps (95% CI: 11,734.14 – 40,260.79).</p> <p>This discrepancy suggests that while patients were ambulatory and engaged in daily activities (as captured by the neck pedometer), the offloading device was not worn consistently, reflecting suboptimal adherence.</p>				

Fig. 3 Pedometer reading in intervention arm



Note: Total number of steps compared between neck and device pedometer in intervention arm using paired t-test

Table 6

Table 6. Difference in user satisfaction between MCR footwear and Offloading device					
Offloading device [Mean (SE)]	MCR footwear [Mean (SE)]	Unadjusted-Mean difference [95% CI]	p-value	Adjusted-Mean difference [95% CI]	p-value
3.90 (0.09)	4.41 (0.08)	-0.51 (-0.75, -0.27)	0.00004	-0.52 (-0.76, -0.28)	0.00003

User satisfaction with the offloading device was significantly lower compared to MCR footwear. Table 6 shows, the mean satisfaction score for MCR footwear was 4.41 (SE: 0.08), while the offloading device scored lower. The unadjusted mean difference was -0.51 (95% CI: -0.75 to -0.27; $p = 0.00004$), and this remained robust after adjustment (-0.52, 95% CI: -0.76 to -0.28; $p = 0.00003$). This indicates that users consistently rated the offloading device less favourably than the standard MCR footwear, suggesting issues related to comfort, usability, or social acceptability.

Table 7

Table 7. Difference in user satisfaction between MCR footwear and Offloading device by Sex and Site					
Sub-group	Category	Offloading device [Mean (SE)]	MCR footwear [Mean (SE)]	Mean difference [95% CI]	p-value
Sex					

Table 7. Difference in user satisfaction between MCR footwear and Offloading device by Sex and Site

Sub-group	Category	Offloading device [Mean (SE)]	MCR footwear [Mean (SE)]	Mean difference [95% CI]	p-value
	Female	3.49 (0.20)	4.35 (0.19)	-0.87 (-1.29, -0.44)	0.00009
	Male	3.89 (0.16)	4.25 (0.16)	-0.36 (-0.64, -0.07)	0.01428
Site					
	India	3.34 (0.17)	4.19 (0.17)	-0.86 (-1.17, -0.54)	0.00000
	Nepal	4.23 (0.18)	4.37 (0.16)	-0.14 (-0.48, 0.20)	0.42437

Table 7 provides insights into subgroup differences. Among women, satisfaction with the offloading device was markedly lower (mean difference -0.87, 95% CI: -1.29 to -0.44; $p = 0.00009$) compared to men (mean difference -0.36, 95% CI: -0.64 to -0.07; $p = 0.01428$). This suggests that female users found the device particularly less acceptable, possibly due to gender-specific mobility needs, cultural expectations, or footwear aesthetics.

Participants in India expressed significantly lower satisfaction with the offloading device compared to MCR footwear (mean difference -0.86, 95% CI: -1.17 to -0.54; $p < 0.001$). In contrast, in Nepal the difference was not statistically significant (mean difference -0.14, 95% CI: -0.48 to 0.20; $p = 0.42437$). This variation may reflect contextual differences in cultural acceptance, footwear practices, or health system guidance for offloading devices.

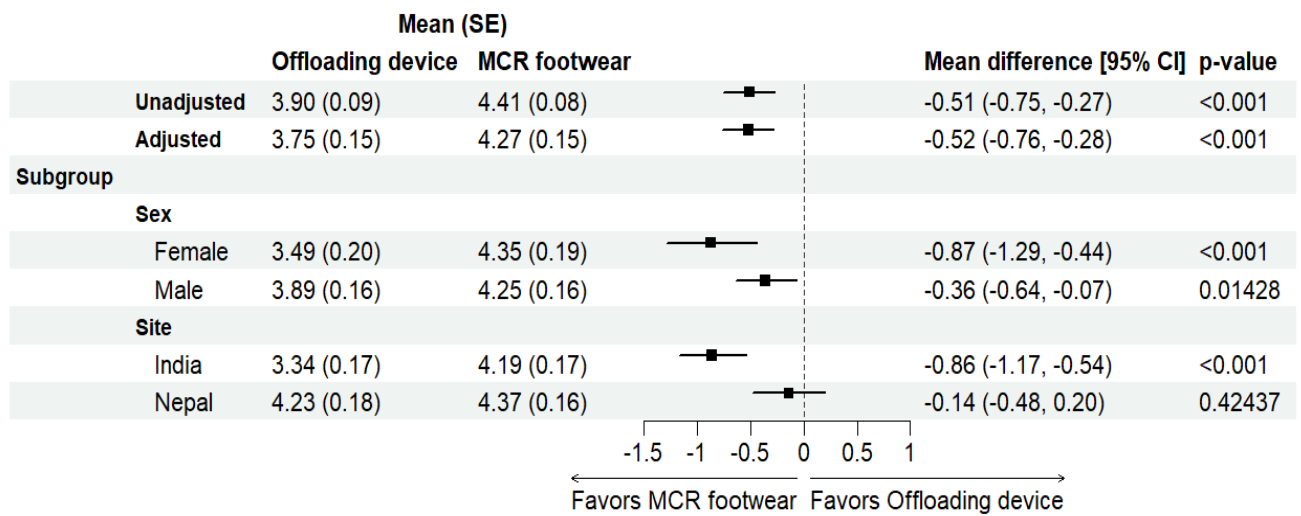
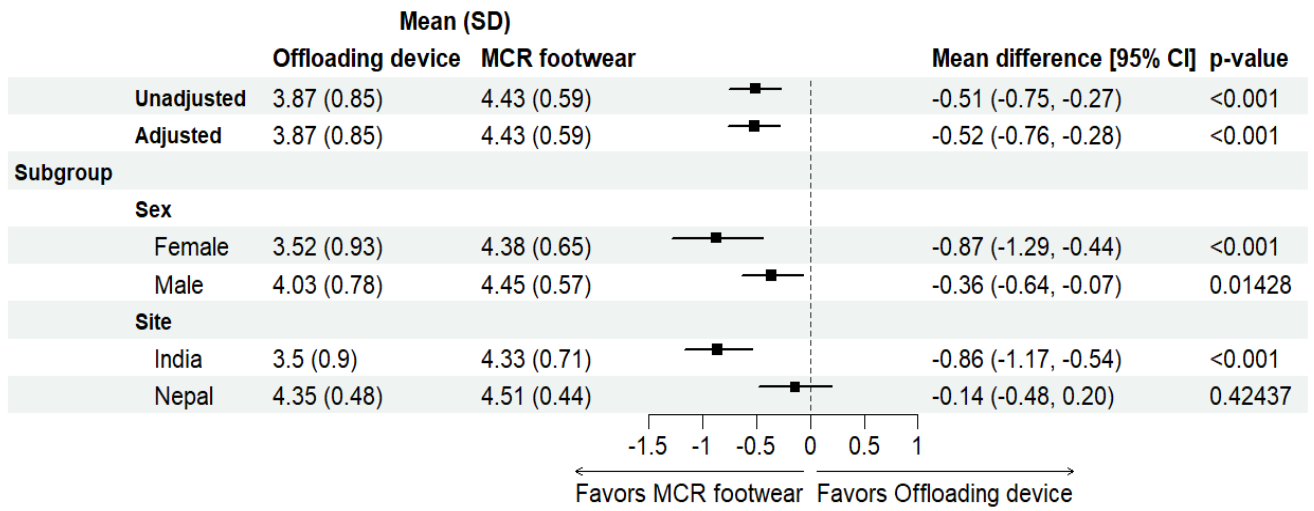


Table 8

Table 8. Difference in healing rates (ulcer area) between MCR footwear and Offloading device					
Offloading device	MCR footwear	Mean difference [95% CI]	p-value	Adjusted-Mean difference [95% CI]	p-value
1.08 (0.20)	1.23 (0.20)	-0.15 (-0.71, 0.41)	0.60268	-0.14 (-0.69, 0.41)	0.61363

Table 9

Characteristic Type of adverse event	Offloading device			MCR footwear		
	Mild (redness) N = 6 ¹	Moderate (redness + blister) N = 3 ¹	Severe (worsening of ulcer-definition) N = 0 ¹	Mild (redness) N = 2 ¹	Moderate (redness + blister) N = 1 ¹	Severe (worsening of ulcer-definition) N = 1 ¹
Redness, solicited	0	0	0	1	0	0
Blister, solicited	1	2	0	0	0	0
Worsening of ulcer (solicited or unsolicited)	0	1	0	0	1	1
Fall, solicited ¹ n	5	0	0	1	0	0