

Patient requires treatment, referred for assessment of eligibility
(n=127)

Excluded (n=0)
Refused to participate (n=5)

Assessed for eligibility
(n=122)

Excluded (n=0)
Not meeting criteria (n=3)
Refused to participate (n=0)

Randomised (n=119)

Allocated to intervention (n=60)
Custom-made functional insole

Allocated to intervention (n=59)
Prefabricated insole

Demographic data collected

Received intervention (n= 56)
1 died
1 moved from area
1 fell and hospitalised long term
1 withdrew from the study

Received intervention (n=57)
1 died
1 amputation of lower extremity

Completing 6-month follow up
(n=53)
Lost to follow-up (n=3)
2 withdrew from study
1 did not attend follow up

Completing 6-month follow up
(n=51)
Lost to follow-up (n=6)
1 died
1 hospitalised terminal illness
1 housebound at follow up
2 withdrew from study
1 did not attend follow up

6 month follow up primary end point (n=104)
kinetic data unavailable (n=8)